

File Number	Submitter	Submitter Category
0135	Anonymous	Private Citizen
0119	Anonymous	Private Citizen
0050	Anonymous (distributor of products)	Industry/Trade Group/Grower/Farmer
0098	Anonymous	Private Citizen
0052	Anonymous (represents Lazy Gator's Hemp Farm)	Industry/Trade Group/Grower/Farmer
0007	Anonymous	Private Citizen
0108	Anonymous	Private Citizen
0088	Anonymous	Private Citizen
0040	L. Mayhew	Private Citizen
0082	Anonymous	Private Citizen
0120	Anonymous	Private Citizen
0099	Anonymous	Private Citizen

Comment summary

Disagree with classifying plant-derived substances as pesticides

Need more research, PBS play vital role in growing cannabis indoors.

Think DG is a change in guidelines, making something a pesticide that was not before, want PBS to be clearly defined. Want free market or in separate category with little to no oversight. Say this will stifle innovation.

HA and kelp shouldn't be pesticides, this is regulatory overreach

Want table 4 out, don't think HFKSE should be pesticides, say the ingredients are all NOP compliant, but this will increase the cost of fertilizers etc

Praise the guidance but write about abiotic stressors impacting fruit yield/size, and say reducing abiotic stress is exempt but fruit yield/size isn't, so this should be exempt since it is due to abiotic stress reduction.

Many humics, kelp, silica products on market not intended for use as pesticides, will hurt market

humic acid and silica aren't pesticides and EPA doesn't justify how they are. Do more research.

various substances are being called pesticides that shouldn't, and they think this guidance is a change in the framework.

Table 4 substances should be exempt. Don't push plant beyond what it can innately do. Small business impacts, too much to label, etc.

Do more research, -ide means kill, these shouldn't be pesticides

"This is ridiculous and not okay. Don't let this happen"

Humic or Fulvic Acid/Kelp/Seaweed Extract/Silica (H, F, K, SE, Si or combo) should be removed/not considered pesticide or are at the least nuanced	Point(s) in RTC that responds (or none or N/A) - some may be addressed in additional points in a tangential manner	Table 4 - Revise or Remove? (is this what commenter wants, not is this EPA's recommendation)
HKSi	Ex. 5 Deliberative Process (DP)	
HK		
HFKSE		remove
HKSESi		
HSi		
HFSE		
HFKSESi		

0047	J. Vaughan	Industry/Trade Group/Grower/Farmer
0145	Anonymous	Private Citizen
0131	Anonymous	Private Citizen
0041	BioAtlantis	Industry/Trade Group/Grower/Farmer
0009	R. and S. Ellis	Industry/Trade Group/Grower/Farmer
0105	Anonymous	Private Citizen
0094	Anonymous	Private Citizen
0113	Anonymous	Private Citizen
0149	T. Lown, Earthgreen Products Inc	Industry/Trade Group/Grower/Farmer
0057	P. Syltie, Vital Earth Resources	Industry/Trade Group/Grower/Farmer
0090	Anonymous	Private Citizen
0026	Anonmyous (commercial plant grower)	Industry/Trade Group/Grower/Farmer

Biostimulants shouldn't be pesticides, thinks this is evidence of chemical industry avoiding natural alternatives, thinks this is a change in regulation
Think guidance is step toward differentiating what is pesticidal/growth regulator, they want allowances for naturally-derived substances that have some ingredients from table 4, mention multiple mechanisms some of which target abiotic stress resistance/relief. Suggest biostimulant class within the minimum risk pesticide listing.
Minimum risk pesticide listing mentioned, mention high level of safety and efficiency
Provided data saying seaweed extracts in their products aren't effective because of hormones, but instead it's just about abiotic stress reduction
their product is not a pesticide but would be treated as one under the guidance. All ingredients are organic and/or food ingredients, labeling as a pesticide will require them to locate another formulator/packager
Document too vague, no specifics as to what natural biostimulants are off topic, mention kelp and fulvic acid are sustainable, farmers can lose important tool, etc. Wants clearer definitions and for some of these natural things to not be treated as pesticides.
These substances aren't pesticides, reclassification will hurt small businesses, and the guidelines should be re-evaluated
Guidelines are ludicrous because these products aren't pesticides, win for "big-agriculture and GMO pushers"
Feel classifying biostimulants as pesticides will have broad and harmful effects, inhibit innovation, impede trend toward sustainable agriculture
Biostimulants shouldn't be pesticides, thinks this is a change in regulation, want them to be freely marketed as non-toxic or in a separate category with little to no oversight.
Think this is a change leading to these substances being pesticides, will harm small business
Commercial plant grower, thinks like of these biostimulants that aren't labeled or registered as pesticides or fertilizers, don't know what's in them, but think what makes them beneficial would be identical to other items registered as pesticide or fertilizer. Thinks EPA should require the registrant to show how product works and what AI is, then determine if AI is a pesticide or a fertilizer.

HFK		
HFK		
SE		
HFK	Ex. 5 Deliberative Process (DP)	
HKSi		
		remove

0087	Anonymous	Private Citizen
0043	Anonymous (rancher)	Industry/Trade Group/Grower/Farmer
0097	Anonymous	Private Citizen
0132	Anonymous	Private Citizen
0086	Anonymous	Private Citizen
0122	Anonymous	Private Citizen
0127	Anonymous	Private Citizen
0117	Anonymous	Private Citizen
0092	Anonymous	Private Citizen
0010	B. Planques, Italtollina USA Inc	Industry/Trade Group/Grower/Farmer
0067	M. Menes, True Organic Products, Inc.	Industry/Trade Group/Grower/Farmer
0048	Anonymous (growing hemp)	Industry/Trade Group/Grower/Farmer
0102	Anonymous	Private Citizen
0114	Anonymous	Private Citizen
0069	P. Barbera, Shoreside Organics	Industry/Trade Group/Grower/Farmer

Do more research before banning such amazing products

Think this is a rule, thinks it is a way for big corporations to bankrupt organic fertilizer movement

Proposal is bad, classifying natural organic products as pesticides harms organic farmers/retailers, this is propaganda from big ag

HSE don't belong in table 4 or as pesticides

HFSE aren't pesticides, this would hurt farmers

HSE shouldn't be regulated as pesticides

Say more study is needed, they've used these substances for gardening for years and "test clean every single time", they aren't pesticides

"-ide" means kill, these aren't pesticides

HK are natural, EPA has no right to regulate, these shouldn't be considered pesticides

extension request

Say HFSE inclusion in Table 4/as Als that need registration as pesticides is inappropriate because the generic raw materials are subject to FIFRA if pesticidal claims are made, and they say the guidance should focus on the claims. Registration of all products containing HFSE will have immediate negative impact on their fertilizer products. They do indicate that the guidance is a change in regulatory structure and registration requirements. They suggest removing Table 4 and focusing on the claims as opposed to the individual materials.

Oppose regulation of organic materials (HFSE) as pesticides,

PBS aren't pesticides and shouldn't need to be regulated as such

Need more research, EPA is trying to regulate things we don't understand, will make things worse for people

Opposes guidance to regulate some organic materials as pesticides, will be costly for what is naturally occurring, this is overregulation

	Ex. 5 Deliberative Process (DP)	
HSE		revise
HFKSE		
HSE		
HK		
HK		
HFSE		remove
HFKSE		

0058	J. Wilson, Atlantic Laboratories, Inc	Industry/Trade Group/Grower/Farmer
0095	Anonymous	Private Citizen
0121	Anonymous	Private Citizen
0128	Anonymous	Private Citizen
0150	Anonymous	Private Citizen
0049	Anonymous	Private Citizen
0110	Anonymous	Private Citizen
0129	R. Hudak, Ag BioTech, Inc.	Industry/Trade Group/Grower/Farmer
0107	Anonymous	Private Citizen
0138	Anonymous	Private Citizen
0136	Anonymous	Private Citizen
0091	Anonymous	Private Citizen
0133	Anonymous	Private Citizen
0093	Anonymous	Private Citizen
0146	Anonymous	Private Citizen
0045	Anonymous	Private Citizen
0103	Anonymous	Private Citizen
0143	Anonymous	Private Citizen

Want label claims considered, say HFSE should be able to be used in fertilizer without pesticide claim, will have economic implications, think this is change in framework (say current is good enough, but what the guidance describes is bad), want table 4 deleted or revised to remove HFSE

These aren't pesticides, this is money grabbing, etc

PBS is broad category, think this focuses on HK, thinks this is based on chem-ag giants lobbying, say proposal is negligent.

HSE don't belong as pesticides, need more research

HSE don't belong as pesticides or in table 4, need more research

Against listing KSE as pesticides that need registration

Against HK being regulated

Wrong to classify PBS with other regulators and pesticides, especially as USDA NOP approves these for organic input. Mention methods through which the biostims work, say including them with pesticides is confusing, will have severe impacts on end users' choices, small business impacts, so PBS shouldn't be included in these "proposed regulations", should either be exempt from registration or in separate category without stringent oversight

Says this is all about money, EPA wants to regulate things that give life as pesticides, refer to this as new regulation

More research needed before putting PBS in same category as pesticides, think this is a regulatory move, say it will affect small farmers

Say proposal is ridiculous, think this is a change

HK shouldn't be considered or used as pesticides, causes undue financial burdens, impacts products already on market, think this increases regulatory hurdles

These are nature, organic, shouldn't be labeled as pesticide, sad this is up for discussion

HK not pesticides, don't need to be regulated as such

Say this is dangerous, hinders organic farmers.

Bad idea, will drive price of organic produce up, say this is attempt by traditional agribusiness lobby

See no reason to lump growth regulators that occur naturally within soil in with pesticides

Request definition of PBS, want guidelines in place to regulate PBS to confirm that the claims actually provide the stated benefits, and having clearer understanding of the intended/potential benefits may provide clarity, and say that while this may increase cost of entry for some, it will provide transparency to growing industry of products for all users

	Ex. 5 Deliberative Process (DP)	
HFSE		remove
HF		
HSE		
HSE		revise
KSE		
HK		
K		
HK		
HSE		
HK		

0044	Dave, Illinois	Private Citizen
0147	Anonymous	Private Citizen
0124	Anonymous	Private Citizen
0125	Anonymous	Private Citizen
0036	Anonymous (work with pesticide and fertilizer registrants)	Industry/Trade Group/Grower/Farmer
0116	Anonymous (soil and crop consultant)	Industry/Trade Group/Grower/Farmer
0008	Anonymous (but they make comments that sound like they're industry-related, ie "our internal report", "industry questions why EPA...")	Industry/Trade Group/Grower/Farmer
0111	Anonymous	Private Citizen
0130	Anonymous	Private Citizen
0144	R. Tribble (listed as Anonymous - says "allow us to continue using kelp and humics without additional fees so I'm putting as industry/trade etc)	Industry/Trade Group/Grower/Farmer
0046	Anonymous	Private Citizen

<p>Opposed to classifying natural fertilizers as pesticide, thinks this changes regulatory approach, impacts small business. Call this "draft regulation", want it to be changed</p>
<p>Including HK is absurd, they're beneficial, aren't pesticides</p>
<p>More research should be done before H foliars are considered pesticides, they're not and aren't harmful</p>
<p>PBS aren't pesticides, agency should prioritize science, no evidence PBS are pesticides</p>
<p>Believes EPA shouldn't regulate PBS or growth regulators, shouldn't have ever been called pesticides, FIFRA should revise/remove sections 2(u) and 2(v), say even by the definition they're not sure why EPA is regulating as pesticides, EPA and FIFRA should focus on chemical pesticides, or EPA needs shortcut way to registration for these, EPA is backed up, etc.</p>
<p>PBS aren't toxic and don't act as pesticides, should not be considered pesticides, only form of regulation (if any) should be to assure toxins aren't combined with them, and if there are no toxins, they should be exempted from EPA regulations.</p>
<p>Say guidance does a good job explaining what compounds should and shouldn't get regulated as pesticides, except for HF, tannins, organic acids from leonardite, since they're part of a normal plant living environment. They shouldn't be in table 4. Say approx 50% of carbon in soil is sequestered in stable forms of humic substances, say regulating these substances would have no impact on human exposure to them, discuss some methodology for measuring fulvic acid components. They mention the current rule at 7 CFR 205.203(d)(2) states that humic and fulvic acids must come from a mined mineral, but they believe that isn't being followed in all cases. Industry questions why EPA is listing humic and fulvic acids in same grouping at CPPA, say there are data showing they behave differently and humic substances shouldn't be regulated as pesticides. Say table 4 should be revised so it doesn't encompass a majority of earth's humus and instead list specific known active compounds without HF, tanins, organic acids from leonardite.</p>
<p>Say this paints with broad brush, is short sighted, going to put small companies out of business because they won't have money to get through red tape</p>
<p>Do more research, no need to rush to regulate biostimulants (like others, think this is regulatory change)</p>
<p>Kelp and humics shouldn't be considered pesticides, protection against pests is indirect not direct, fees will be detrimental to farmers everywhere</p>
<p>HFSE are valuable soil additions, shouldn't be registered as pesticides, which will diminish their availability which is concerning to organic farmers, want organic products kept out of pesticide registration</p>

	Ex. 5 Deliberative Process (DP)	
HK		
H		
HF		revise
HK		
HFSE		

0123	Anonymous	Private Citizen
0126	Anonymous	Private Citizen
0118	Anonymous	Private Citizen
0115	Anonymous (kept as private citizen bc they say gardener, not farmer, but questionable given the cannabis reference?)	Private Citizen
0085	Advanced Nutrients US LLC (coded as Anonymous)	Industry/Trade Group/Grower/Farmer
0053	Anonymous	Private Citizen
0039	Nancy Burke, Saul Ewing Arnstein & Lehr on behalf of Pioneer Peat, Inc.	Industry/Trade Group/Grower/Farmer
0084	K. Dodd	Private Citizen

These compounds aren't pesticides, are soil amendments, you'll harm farmers by regulating them.
HSE don't belong on table 4, more research needed.
PBS aren't pesticides, don't have any of the same MOA, this regulation doesn't make sense, says this is EPA looking to create another barrier
HSE shouldn't be considered pesticides, they're an organic gardener and use kelp products, say they're normally already OMRI and NOP listed, think additional research needed, further discourse about what industries EPA is trying to regulate, and some of these products are in vegan soil mixes and favored by cannabis growers
HFKSE shouldn't be registered as pesticides unless label claims are made, shouldn't be on Table 4 specifically identified as plant regulators subject to FIFRA. Also oppose Bt as pesticide ingredient unless pesticide label claims are made, as the microbe is recognized as an ingredient under fertilizer regulatory oversight and should stay there, not FIFRA
SE should be exempt because they're not pesticides, labeling them as such may prohibit their use by organic gardeners, industry impacts, gave some history of seaweed use, just because it's a biostimulant doesn't mean it needs to be regulated, thinks this traces back to chemical fertilizer industry, says these are vegetable extracts not pesticide
Commenting on behalf of a company that produces and sells natural soil amendments for improvement, maintenance, survival, etc of plants. They oppose the guidance saying it unreasonably limits the claims that producers may make for their products, ignoring the full import of the statutory exceptions to the definition of plant regulator. Under FIFRA 2(v), is says plant regulator shall not include substances intended as plant nutrients, trace elements, nutritional chems, plant inoculants, soil amendments and also shall not be required to include any of the nutrient mixtures/soil amendments commonly known as vitamin-hormone horticultural products. They want producers to be able to make such claims about their products - concerned about products being unfairly limited in their claims because improving plant health will also promote plant growth/development. Also says humic acids shouldn't be included since they're inherent to soil and peat. Also say this guidance captures exempt products and would "regulate plain old dirt as a pesticide". Say the guidance is designed to benefit large companies, discourage small businesses.
Want seaweed extracts and kelp to be considered fertilizers, excluded from FIFRA requirements, cite long history of safe use, registration as fertilizer in states, etc.

	Ex. 5 Deliberative Process (DP)	
HSE		revise
HKSE		
HFKSE		revise
SE		
H		
KSE		

0038	Anonymous	Private Citizen
0148	Anonymous	Private Citizen
0100	Anonymous	Private Citizen
0033	Anonymous (Commercial scale produce grower)	Industry/Trade Group/Grower/Farmer
0106	Anonymous	Private Citizen
0137	Anonymous	Private Citizen
0109	Anonymous	Private Citizen
0104	Anonymous	Private Citizen
0089	Anonymous	Private Citizen
0112	Anonymous	Private Citizen
0006	Anonymous	Private Citizen
0101	Anonymous (refers to self as farmer)	Industry/Trade Group/Grower/Farmer

Say seaweeds themselves are not AIs, though some seaweed-based products are registered as plant regulators, say there's a concern with listing SE in Table 4. Specifically call out the lack of chemical characterization, identification of multiple MOA, whether or not the biostimulant/growth regulator claims are adequate. Concerns are explained in more detail, but highlights: definition of SE is not verifiable due to diversity of seaweeds, not all have bioactive response when applied to plants, their complexity makes it difficult to ascribe plant responses to specific regulators, gives some example MOAs, say SE shouldn't be assumed to have a unique MOA similar to registered plant regulators. Finally, say the effects of SE are better represented by claims that are not regulator claims, better first nutrition-based claimed or non-pesticidal claims. Want consistent biostim definition to what is used by USDA in report to congress.

Say this change in classification without further research would be costly and careless, say these are natural fertilizers and soil conditioners, not pesticides, changes would hurt small family farmers.

Thinks this is change in regulation, want it to be reconsidered, says we have enough regulation as is, and as long as "it is sustainably mined it should be ok"

They use biostims, strongly oppose regulation of biostims, say there is nothing harmful, and it's the harmful nature of pesticides that requires regulation, some are very effective and increase growth at least 10%, worried some will be taken off market or go up in price. Also say biostims are totally different from PGRs, which are unnatural and highly developed to imitate nature. PGRs should be regulated, but biostims shouldn't.

"This needs to be looked at more before just banning"

Humic acids aren't CPPAs, and without testing methodology, don't see how EPA can issue such guidance. Want humic acid and SE off of Table 4.

"This is bull crap"

"Keep it organic and natural"

Kelp, silica, other biostim are not and shouldn't be regulated like pesticides

Want one good reason naturally-occurring biological additives should be grouped with pesticides, say whoever is benefitting/profitting off of this isn't the consumer

No products like these should be used until "us dept of health" investigated the effects of eating plants grown with this new product, say this is using Americans as guinea pigs, say USDA is out for profiteering, doesn't care who dies as a result

Disagrees with "this claim", says biostims need to be studied more before the government classifies them as a pesticide, says "we (the farmers)" use these products more than anyone and know what they are truly capable of.

SE		revise
	Ex. 5 Deliberative Process (DP)	
HSE		Revise
KSi		

0134	Anonymous	Private Citizen
0142	Anonymous	Private Citizen
0022	Catherine Bishop, Lebanon Seaboard Corp	Industry/Trade Group/Grower/Farmer
0080	D. Hiltz, Acadian Seaplants	Industry/Trade Group/Grower/Farmer
0060	J. Breen, Actagro	Industry/Trade Group/Grower/Farmer

Please don't over-regulate environmentally-friendly products like HK, no evidence that harvest or use of these harms environment and they are great tools for making dead soil fallow and useful for growing food crops.

"More research is needed"

extension request

Fully support comments submitted by BPIA and USBC, also members of EBIC and have worked for years to define new regulatory environment for PBS in EU. Thinks that as written, this guidance may create more confusion, concerned that state regulatory agencies, industry, and other stakeholders will keep having questions about how PBS should be registered. Point of Table 4 with mention of HSE would have huge regulatory burden. Want more clarity around definition of plant regulator, guidance should include claims-based approach, implied classification of certain well-established PBS as pesticides is not aligned with global regulation, and economic impact would be high. Detailed the requests more in letter - call out that growth regulator needs to alter/modify growth habit in a way that it would not normally behave under optimal growing conditions, and say PBS are neither intended nor claimed to alter/modify normal growth habits. Want clear PBS definition. Say Table 4 introduces substance-based criteria in addition to claims-based, and it is oversimplified. Mention that many table 4 registrations are very old, were useful at that time for national consistency. Want "nutritional chemical" both defined and excluded from PGR definition.

Comments in 5 categories: ongoing regulatory uncertainty, impacts on innovation, economic implications, market access for PBS products, and accessibility for end users. Ongoing reg uncertainty included claims-based regulation - significant overlap/shared language with -0080. As alternate to deleting table 4, suggest language saying that although these substances have been selected for FIFRA reg by some companies, they may not be required to be registered depending on the conditions described in FIFRA and lines 101-105 of the guidance. Also mention potential conflicts with other federal efforts like USDA report to congress and quantify some of their estimated economic impacts if the guidance is implemented as written.

HK	Ex. 5 Deliberative Process (DP)	
HFSE		remove
		remove

0156	P. Mullins, Brandon Products	Industry/Trade Group/Grower/Farmer
0031	T. Stopyra, Intl Agribusiness Consultants	Industry/Trade Group/Grower/Farmer
0013	R. Taylor, Humic Products Trade Assoc	Industry/Trade Group/Grower/Farmer
0012	D. Pearce, Pathway BioLogic	Industry/Trade Group/Grower/Farmer
0166	M. Key, Impello Biosciences	Industry/Trade Group/Grower/Farmer
0023	S. Van Wert, Bayer CropScience	Industry/Trade Group/Grower/Farmer

Concerned mostly about seaweed/SE, say it's unclear if including SE on Table 4 means it must be registered under FIFRA, as there are numerous examples of it being sold for nutritional/biostim effects. Say it needs to be made clear that materials registered under FIFRA are not prevented from being marketed as biostims outside of the scope of FIFRA. Mention inhibition of innovation, economic impacts on sm/med biz, deprive growers, say much of the data for SE under FIFRA was pre-2000, based on outdated methodology, applied at such low level that the hormones can't have the PGR effects. Say 152.15 2 b would be good safeguard to make sure pesticides don't get to market incorrectly. Include appendices countering some of the basis of assessment on SE composition, effects of nutrients acting in PGR-like manner.

Main problem is defining what constitutes a PGR - say random testimonials aren't sufficient as basis of claim. Use of seaweeds goes back centuries. Say Table 4 is incomplete, will generate confusion among prospective registrants - footnotes fail to adequately define what are naturally occurring PGRs given that some must be artificially synthesized. Think addition of info on rate/quantity required for effect, as PGRs should act at lower levels than nutrients. Say including long list of PBS as PGR will create confusion, economic hardship. Says EPA is probably ill-prepared to receive dozens of applications for these and to respond in timely manner. Say full impact won't be known until EPA implements the guidance.

extension request

extension request

Specializes in R&D of plant biostims, focusing on plant growth promoting rhizobacteria (PGPR) and beneficial microbes. Comments call into 5 categories - ongoing reg uncertainty, impacts on innovation, economic implications, market access for PBS, accessibility for end users - lots of overlap with -0060. They also call out the proposed differentiation of methods of delivery, which introduces confusion and inconsistencies - say it's inaccurate to assume a single ingredient can be pesticidal and non-pesticidal depending on method of delivery, mention claims-based review. Say PBS is helping to revive the ag industry overall.

extension request

SE		
	Ex. 5 Deliberative Process (DP)	
HFSE		
		remove

0066	D. Woods, CA Dept of Food & Ag	US State
0037	D. Vanderhoff, Chamberlin Ag	Industry/Trade Group/Grower/Farmer
0027	M. Siddoway, BioSaphe	Industry/Trade Group/Grower/Farmer
0016	D. Beaudreau, US Biostimulant Coalition	Industry/Trade Group/Grower/Farmer
0055	S. Lebo, Sustainable AGRO Solutions, LignoTech USA	Industry/Trade Group/Grower/Farmer
0077	J. Sooby, CCOF	Industry/Trade Group/Grower/Farmer

Note that some label claims in guidance appear to be interpreted differently by CDFA and EPA. Mention the Fertilizing Materials Inspection Branch which oversees and enforces regulations related to fertilizing materials. They note areas of disagreement, like Table 3: some of the examples go beyond pesticide action, like enhances/promotes/stimulates plant growth and dev or fruit growth and dev, which overlaps with CDFA's definition of commercial fertilizer, Table 4 includes ingredients in widespread use in foliar fertilizing material products (list SE, H, Si). Want to know if products like SE and H are a priori pesticides or if it depends on label claims. They don't think EPA needs to define biostimulant at this point.

PBS aren't PGR and therefore aren't pesticides and shouldn't be subject to FIFRA. Products will be inhibited, reducing farmers' ability to increase sustainability and productivity, USDA already wrote definition of PBS, think that EPA wants to use rulemaking to make PBS subject to FIFRA, reference label review manual with regard to claims-based approach, note that PGR needs to go beyond "simple plant nutrition" which is not defined.

extension request

extension request

Letter appears to have been drafted by Humic Products Trade Assoc. Want definition of PBS as presented in 2018 Farm Bill to be clarified, and EPA wants to align with the definition in the USDA report to Congress, says EPA should wait before finalizing. Mentions history of why some would want to get FIFRA registration to satisfy complicated state registrations. They have specific expertise in HF, listed in Table 4. They agree that soil amendment exemptions for soil-applied HFs should be maintained, but disagree with the proposed language in draft that restricts foliar-applied HF. Say compositional differences should be considered, bring up use of CPPA category, discrepancies in what may actually be registered vs other products. Say guidance doesn't consider the exemptions at 152.15a-c, regarding other commercially valuable uses. Say Humic substances are used for non-pesticidal uses with significant commercial value. They say there will be added burden as a result of guidance even though EPA says otherwise.

Org advocates for organic policies. Think this guidance will result in certified organic producers losing access to important tools with decades of safe use. Want HFSE removed from table 4 since they're listed as ingredients that are required to be registered as pesticides - says they're proposed to be classified as PGRs. They agree that the products that contain these and are specifically formulated and labeled for PGR use should be regulated as pesticides, but when just used as foliar nutrients or delivery matrix to carry nutrients, which shouldn't be classified as pesticides. Organic fertilizers containing these substances are currently exempt, and they say they should continue to be exempt. Say organic farming is already well-regulated under USDA's NOP.

	Ex. 5 Deliberative Process (DP)	
HSESi		
	Ex. 5 Deliberative Process (DP)	
HF		remove
HFSE		revise

0141	J. Buck, Bio-Gro Inc	Industry/Trade Group/Grower/Farmer
0152	W. Harrell, Harrell's	Industry/Trade Group/Grower/Farmer
0074	E. Thomas, The Fertilizer Institute	Industry/Trade Group/Grower/Farmer
0162	C. Kamberg, TriYield	Industry/Trade Group/Grower/Farmer
0153	J. MacKay, Cool Planet Energy Systems	Industry/Trade Group/Grower/Farmer

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Very similar to some other letters (0080, 0060) - split into 5 categories, ongoing reg uncertainties, impacts on innovation, economic implications, market access for PBS, accessibility for end users. No new info that doesn't appear in the others.

TFI represents fertilizer industry, and PBS are routinely blended with fertilizers or retailed as supplemental products. TFI is concerned that, as written, the guidance imposes requirements that go beyond the intent of FIFRA. Say PBS aren't plant regulators (or fertilizers). 1. want table 4 removed - say claims-based approach is reasonable and including which claims are and aren't PGR makes sense, but then table 4 lists substances regardless of claim - say it's deviation from claims-based approach. Concerned about misinterpretation of table 4 - say it is oversimplification of the actual requirements of the law. 2. want clarification on FIFRA exclusion provisions (re: plant nutrients, trace elements, nutritional chems, plant inoculants, soil amendments). They say PBS' are innovative products that Congress envisioned when crafting FIFRA and thought they'd go in plant inoculant/nutritional chem categories and want clarification on the intent of Congress' use of the term nutritional chemicals (and say that non-microbial PBS generally meet nutritional chem exclusion - they also offer an interpretive definition). 3. consult with USDA. Don't define PBS until USDA and stakeholders (with EPA) work together to develop one. Don't want EPA to finalize guidance yet.

Similar to 0080, 0060, 0152.

Supplier of biochar, member of Biostim Coalition and Crop Life America, support comments from both. Consider PBS distinct from PGR, say the intentions/claims are to support optimal nutritional processes that enable plant to realize its innate genetic growth potential. Want clearer def of PGR. Say global regulation of PBS is moving towards claims-based approach, treatment as fertilizer. Think lines 267-268 defining nutritional chems thinks many PBS would fall into that category, want EPA to define all statutory exclusions, includ possible definition for nutr chem. Also want EPA to revisit current prohibition on using vitamin hormone products on food sites. Say it's premature for EPA to define PBS.

HF		Ex. 5 Deliberative Process (DP)	remove		
			remove		
HF			remove		
			remove		
			remove		

0155	J. Restum, Scotts Miracle-Gro Co	Industry/Trade Group/Grower/Farmer
0139	K. Reardon, Responsible Industry for a Sound Environment	Industry/Trade Group/Grower/Farmer
0070	L. Bonini, European Biostimulants Industry Council	Non-US Trade Association

Supportive of clarification, but want substantial revisions. Say EPA's proposed definition of PBS is inconsistent with others, there's contradiction with respect to plant regulator claims vs plant nutrients, soil amendments and inoculants. Want EPA to postpone rulemaking to define PBS until a federal definition is finalized as envisioned by Congress, differentiate the effect of PRs from natural stimulation and growth enhancement resulting from optimal nutrition, and eliminate list-based guidance by deleting table 4. Go into more detail on each of these. Call out that EPA limits PBS to naturally-occurring and missed synthetic analogs, implying that they're subject to registration as regulators. Also mention impacts on mixing with inorganic/synthetic fertilizers. Want changes in earlier tables, basically saying there's a lack of clarity around some of the growth claims and what does/doesn't require registration. Say the tables are helpful in understanding EPA's intent but don't align with regulations. Say Table 3 should be narrowed to only list claims that are strictly consistent with regulator def in FIFRA 2(v). Want title of Table 1a to be changed to specify nutrition-based claims (necessary for normal plant growth). Say table 4 creates list-based approach, doesn't recognize MOA or intent, erroneously includes plant food ingredients, and shouldn't differentiate between foliar and soil applications. Says proposed guidance doesn't account for concentration needed for something to be biologically active. Mention especially for H that it's unclear of physiological MOA when applied as foliar fertilizer, so classifying them as pesticides that way is unsupported by the literature.

Similar to some others. Talk about various uses of PBS in ag and non-ag applications, don't want PBS treated as pesticides. 1. claims-based reg approach: think this isn't reflected here, want table 4 removed. Say something is only a pesticide if such a claim is made, and table 4 strays from that. Say dual use concept (pesticide + non-pesticide) should be included in guidance. Table 4 doesn't provide clarity to manufacturers seeking to maintain compliance, it just re-states public info. mention EU treatment of biostims more like fertilizers. Want clarification that other tables aren't comprehensive, suggest clarity on some examples ie enhances/promotes phrasing is overly broad, want them removed from table 3 (bullets 1, 2, 14, 15). Want coordination with other agencies and to wait for definition until after USDA and other stakeholders weigh in. Potential negative effects of proposed guidance: impacts on innovation and companies in biostim market. Think it's shift in regulatory framework. Want table 4 out since they think it requires addl registrations.

Similar to some others. Broad topics: guidance should respect claims-based approach, economic implications could inhibit innovation, and finalization should be delayed to allow for coordination with USDA on relevant aspects of Ag Improvement Act of 2018. Want it spelled out that the tables 1-3 aren't comprehensive. Table 4 should be removed because of claims-based issues and confusion. Think changes from the guidance could hurt the R&D of PBS and other innovation. Want EPA to wait to finalize.

HFKSESi	Ex. 5 Deliberative Process (DP)	remove
		remove
HSE		remove

0018	P. Perez, PlantResponse Biotech	Industry/Trade Group/Grower/Farmer
0035	R. Welsh, Law Office of R. Welsh	Industry/Trade Group/Grower/Farmer
0159	C. Wolfe, FBSciences	Industry/Trade Group/Grower/Farmer
0079	E. Chandler, Thorvin, Inc	Industry/Trade Group/Grower/Farmer
0061	K. Pitts, Marrone Bio Innovations	Industry/Trade Group/Grower/Farmer
0161	D. Beaudreau + K. Jones, US Biostim Coalition and Biol Products Industry Alliance	Industry/Trade Group/Grower/Farmer
0017	R. McDonald, BioLiNE	Industry/Trade Group/Grower/Farmer

Want seaweed extracts and kelp to be considered fertilizers, excluded from FIFRA requirements, cite long history of safe use, registration as fertilizer in states, etc.

Want streamlined process, ideally exempting PBS from registration. Mention confusion from some of the issues (ie how is "improves nutrient assimilation" different from "enhances fruit growth and development" since presumably one could lead to the other)

They registered CPPAs (bullet 5 of table 4), and along with it but incorrectly associated is humic acid, fulvic acid, tannins, organic acids from leonardite. They say CPPA is exclusive to FBSciences, they use proprietary manufacturing process, it's not a generic class of substances. They want Table 4 revised so CPPA is separated from other organic acids

HFSE as generic raw materials should not trigger registration as pesticides. They're frequently used as fertilizer ingredients. Should only be subject to FIFRA if pesticidal claims are made. The guidance should focus on claims.

Similar to 0080, 0060, 0152, 0162.

Very extensive comments, including line by line suggestions. Serve as basis for 0060, 0080, 0152, 0162, 0061, and others. Included 15 page proposed addition to the guidance addressing nutritional chemicals excluded from the definition of plant regulators. A lot about optimal growing conditions and how PBS aid a plant without going beyond those limits (innate growth potential etc). Mention dual use situation (as a pesticide and not based on claims). Want clarity on definition of plant regulator in guidance, including decision tree idea. They also include historical perspective on how some things were registered, calling inclusion of HFSE especially problematic. Say that assuming a raw material will also be processed to be made into a pesticide is unreasonable. Also include in depth economic analyses.

extension request

	Ex. 5 Deliberative Process (DP)	
		revise
HFSE		revise or remove
HF		remove
HFSE		remove

0165	J. Skillen, Lawn & Horticultural Products Work Group	Industry/Trade Group/Grower/Farmer
0042	P. Miars, Organic Materials Review Institute	Industry/Trade Group/Grower/Farmer
0140	S. McCarty, Helena Agri-Enterprises, LLC	Industry/Trade Group/Grower/Farmer
0073	D. Benmhend, FMC Corporation	Industry/Trade Group/Grower/Farmer
0032	J. MacKay, Cool Planet Energy Systems	Industry/Trade Group/Grower/Farmer

Incorporation of PBS into specialty consumer products is rapidly growing. Say DG has lots of info but little guidance. Want agency to include decision tree, and they drafted one. Mention states' role in regulating fertilizers. Propose a slightly narrower definition of PBS, mention that EPA does not have its own definition of plant hormones - ask if it's "naturally occurring hormones extracted from algae, such as auxins, cytokinins, and gibberellins". Think EPA should consider revising all definitions under what's exempt, ie plant nutrients, inoculants, soil amendments. Point out lack of clarity by including SE on Table 4 as pesticides, but then saying they don't have a defined content of PGRs and might reasonably be vitamin-hormone products. Spell out why a grower would want to use PGRs: to control/delay abscission/development/ripening/senescence, induce/promote/retard/suppress flowering, induce/promote/retard/suppress bud break, or induce/promote/retard/suppress seed germination. They suggest defining PGRs as substance or mixture of substances that, once applied, alter through physiological action the normal development of the target plant(s) to benefit the grower.

Say the DG clarifies that PBS should be considered PGRs. Say name and executive summary suggest purpose of guidance is to help stakeholders identify pesticidal label claims, but DG expands beyond that when it says label claims alone are not the only criteria that should be used when identifying PGRs subject to registration as pesticides. The include suggested deletions and additions to executive summary for clarity. Suggested edits are addressed in doc. Want text introducing table 4 to change, say that the table impacts many of the products they list as crop fertilizer and soil amendment products. Say guidance could result in several hundred new registrations.

Want clarity on exactly what claims require EPA registration. Say clearer definition of PBS would take away the guesswork when categorizing document as PBS or PGR. Think industry and EPA should work together to do that.

Similar to 0080, 0060, 0152, 0162, 0061. Say other countries are leading the way with progressive regulations for PBS, while EPA's additional regulations will be burdensome and make technologies less available. Also suggest regulatory harmonization to facilitate trade.

extension request

	Ex. 5 Deliberative Process (DP)	
		revise
HF		remove

0158	G. Beattie, Phytopathological Society Public Policy Board	Industry/Trade Group/Grower/Farmer
0071	M. Fraley, Seawin USA, Inc	Industry/Trade Group/Grower/Farmer
0030	J. Ott, Nevada Dept of Ag	US State
0056	H. Damm, Damm Corporation	Industry/Trade Group/Grower/Farmer

Nonprofit scientific organization. Definition of PBS: no single definition is currently universally accepted or serves as a legal definition under FIFRA. They say EPA should wait for coordinated definition to be agreed upon as result of Farm Bill. After that, legal definition is needed so a reasonable regulatory framework can be established. They acknowledge that claims are key consideration but other factors including ai, intended uses, etc are also considered in determining if a pesticide - but that said, they think table 4 may trigger unwarranted hurdles by authorities (like at state level), and say a list of MOA that trigger regulation under FIFRA would be more accurate and get away from fear of a substance-based approach. Talk about difficulty differentiating between growth enhancement (non-FIFRA) and growth regulation (FIFRA), especially as some function in tolerance to abiotic AND biotic stresses. Suggest EPA, USDA, and stakeholders work together for appropriate and sensible regulation. Requested editorial change at line 53 - description of PBS which they say is poor representation of some PBS (ie rhizobia provide N which is a fertilizer benefit, but PBS description in DG says PBS do not provide any nutritionally relevant fertilizer benefit (this was slightly edited in updated DG on p 4 in background).

Similar to 0080, 0060, 0152, 0162, 0061, 0073

Want clearer definition of PBS - note that there are apparent discrepancies between 2018 Farm Bill definition and EPA's description in the DG, specifically noting that farm bill seems to have one overall category but EPA splits it into pesticidal and non-pesticidal. They note that both non-pesticidal product labels and those that trigger regulation under FIFRA has synonymous descriptors that also appear in the farm bill definition.

Sell liquid fertilizers to organic market, and several of the blends include HFSE. They're opposed to including those as pesticides - say using these substances as generic raw materials shouldn't trigger oversight. Want guidance to focus on product claims, not meterly presence of these ingredients. Very similar to earlier comment (0079)... say as long as no pesticidal claims, shouldn't need to be registered. Want table 4 either revised or removed. Also want clear definition of PBS. Specific questions: does amount of plant regulator make a difference? At what volume, weight, or concen is a PR effective? How will EPA coordinate with States, NOP, or AAPFCO requirements? When will EPA or appropriate agency define PBS?

	Ex. 5 Deliberative Process (DP)	remove
HF		remove
HFSE		revise or remove

0160	R. Kachadoorian and L. Reed, AAPCO	State Association of Regulatory Officials
0059	R. McDonald, BioLiNE	Industry/Trade Group/Grower/Farmer
0014	E. Scott, Actagro	Industry/Trade Group/Grower/Farmer
0083	B. Wolf, Wolf, DiMatteo + Associates	Industry/Trade Group/Grower/Farmer
0051	Anonymous	Private Citizen

Say state pesticide and fertilizer laws determine if product requires registration. Want effective and consistent regulatory action at state and federal levels. Say more exempt categories results in increased burden on states. They're in favor of requiring registration. Want details and references in table 4 expanded, enforceable language added, details on what enforcement would look like, ensure that reference tables can be edited and updated without opening rulemaking process, and provide clarity on what products can be used on food or feed crops, tolerance issues, etc. Say microbial biostimulants have not been adequately addressed. Want a "PRIA Lite" review framework for biostims. They're glad table 4 is present.

Similar to 0080, 0060, 0152, 0162, 0061, 0073, 0071

extension request

Involved in organic ag for over 30 years, see no issues with proper use of HFSE, want either generic materials (HFSE) removed from table 4 or table 4 deleted. Similar to 0056 and 0079. Say these generic raw materials are often used in fertilizers without pesticidal claims, guidance should focus on product claims, not the inclusion of specific substances. Say products containing these that DO make PGR claims should be registered as pesticides, but others shouldn't.

Say confusion arises because of inclusion of SE in table 4, as there are many types of SE with diff chemical compositions and no universally accepted MOA. Mention the varying concentrations of things like auxins, cytokinins, gibberellins, and the fact that SE also contain carbohydrates, trace elements, AAs, vitamins, nutrients, etc, all of which vary based on source/timing of harvest, and there's no clear understanding of what component plays what role on plant health. Therefore it isn't appropriate for EPA to consider all SE subject to FIFRA on MOA basis. Mention that DG says PBS are relatively new, but SE have been used for centuries. Mention that many effects of SE could be considered non-pesticidal. Say SE have been considered plant nutrients for years. Mention what other commenters have said, including that it's not clear if the benefits of using SE are from the presence of phytohormones that appear to be triggering PGR consideration. Want SE out of table 4. Also say SE should be added to minimum risk pesticides.

HF		remove
HFSE	Ex. 5 Deliberative Process (DP)	revise or remove
SE		revise

0163	BASF	Industry/Trade Group/Grower/Farmer
0028	Y. Fuentes, BioSafe Systems	Industry/Trade Group/Grower/Farmer
0024	C. Mamone, Indigo Agriculture	Industry/Trade Group/Grower/Farmer
0072	S. Van Wert, Bayer CropScience	Industry/Trade Group/Grower/Farmer
0015	K. Jones, Biological Products Industry Alliance	Industry/Trade Group/Grower/Farmer
0025	M. Key, Impello Biosciences	Industry/Trade Group/Grower/Farmer
0064	Agricultural Retailers Association et al.	Industry/Trade Group/Grower/Farmer

Support the comments of Biological Product Industry Alliance (BPIA) and Biostimulant Coalition (BC) comments. Also have some specific comments: lines 104 and 110 want amended to include concept of commercially efficacious pesticide, as low level pesticidal activity is not commercially relevant and shouldn't be regulated under FIFRA. lines 134-141 - want definition amended to account for microbial secondary metabolites that may function as vitamin hormones but would be excluded from category. Also want table 4 removed, saying it doesn't align with the DG saying it's intended to provide guidance on identifying product label claims that are considered to be PR claims by agency", since the table is substance-based not claims-based.

extension request

extension request

Want EPA to wait and work with USDA on definition for PBS. Want language added to make it clear that tables 1-3 aren't comprehensive, which was done. Want better clarify on what is a PR and what's excluded under FIFRA. Want table 4 removed. Suggest decision tree be added. List specific changes, line by line, including removal of "naturally occurring" as it's undefined and could limit future innovation/technology advancements, say diff definitions of PBS occur at lines 48-50 and 75-79, want EU fertilizers definition included for PBS, note other inconsistencies about plant growth (ie growth of whole plant is fine but of specific parts isn't), want guidance to address situations where there are multiple MOA and some fall outside FIFRA, say "enhances plant growth and development" as PR claim is too broad since it also applies to nutrients, inoculents, soil amendments, want term deleted from table 3. Also stand by BPIA and BC comments.

extension request

extension request

Similar to 0080, 0060, 0152, 0162, 0061, 0073, 0071, 0059, but include economic impact appendix.

		remove
	Ex. 5 Deliberative Process (DP)	
		remove
		remove

0075	K. Davis, WA State Dept of Ag	US State
0065	G. de la Borda, Stoller Enterprises	Industry/Trade Group/Grower/Farmer
0020	S. Lebo, Sustainable AGRO Solutions, LignoTech USA	Industry/Trade Group/Grower/Farmer
0063	D. Middleton, Ocean Organics Corporation	Industry/Trade Group/Grower/Farmer
0076	L. Bunderson, Aqua-Yield Operations LLC	Industry/Trade Group/Grower/Farmer
0054	L. Bunderson, Aqua-Yield Operations LLC	Industry/Trade Group/Grower/Farmer

Say guidance will be useful to State staff regulating pesticides and fertilizers. Say table 4 is one of the most valuable parts as it makes clear that certain ingredients are pesticides and should be regulated as such. Some line by line comments, including that the guidance doesn't cover all types of PBS like some Bacillus strains - want adding "or biopesticides" after "plant regulators". Want us to wait to develop PBS definition, point out that PBS aren't new and reference 1993 registered product calls a biostimulant. Say not all PBS are natural so that should be removed from EPA's description - they provide some suggested edits/additions. Want it clearly stated that biostimulant is, not by itself, a pesticide claim - want additional clarity. Want MOA considered in addition to label claims, say many PBS products include claims for secondary effect that aren't pesticidal, but MOA of product is as pesticide (example: hormone to increase root growth by MOA, but label claim is increased nutrient uptake). Table 1a - "soil" in several bullets should be removed from 1a and moved to 1c. Request clarification around what "behaviors" are included as physiological actions. Promotion of plant growth can be a nutrient/fertilizer claim. Table 4 question - do the ingredients need to be associated with pesticide claims on label/labeling to be considered pesticide? Lots of table 4 comments regarding clarification (but say it needs to stay).

Want clarified that tables 1-3 aren't comprehensive. Table 4 appears to trigger registration, and they support the table and in particular the inclusion of SE, which they acknowledge is a complicated case as there are cases where it was used in products described as fertilizers or vit-hormone products. Want EPA to review the USDA report to congress for PBS definition and then incorporate based on that. Say there will be economic benefits from DG because of clarity provided to states, producers, growers, etc.

extension request

Support other comments, and say they have a few points of their own. Say Table 4 goes beyond being claims-based and is inappropriate, too far-reaching. Would damage their company because they use HFSE in non-pesticidal ways. Say SE support natural plant nutrition processes, saying their role isn't as PR. They mention concentration issues and that PRs are meant to be pure and used at specific concentrations.

Similar to 0080, 0060, 0152, 0162, 0061, 0073, 0071, 0059, 0064

Similar to 0080, 0060, 0152, 0162, 0061, 0073, 0071, 0059, 0064, 0076

HFSESi	Ex. 5 Deliberative Process (DP)	
HFSE		remove
		remove
		remove

0151	J. Mirenda, Organic Trade Association	Industry/Trade Group/Grower/Farmer
0157	B. Glenn, Natl Assn of State Depts of Ag	State Association of Regulatory Officials

Have questions about purpose and intent of Table 4, whether it means all products containing those ingredients are automatically subject to FIFRA regulation regardless of claims/intended use, if that's the case they have concerns about alignment with EPA policies, USDA organic regs, and impact on organic ag sector. They support further coord with USDA to provide clarity on PBS. Table 4-specific comments: it doesn't mention claims at all and doesn't say whether other products need to be registered - unclear impacts. Want clarity around the purpose of Table 4, how it relates to earlier tables (ie is table 4 intended to list ingredients that MAY be subject to FIFRA IF they also have label claims matching table 3?) They've provided labels of things that contain ingredients from Table 4 but no claims similar to Table 3. Quote parts of CFR re: "intended to..." part of PR definition, claims/states/implies use for pesticidal purpose parts. Propose removing Table 4, but also say if instead it stays in, its purpose must be clarified and EPA must encuse that Table 4 is an exhaustive, inclusive list of all affected substances. Propose new name to add "...and associated product label claims..." in it. Also want PBS definition to be aligned with USDA report to congress.

Say guidance falls short of the clarity they need, and instead they need a clear, transparent, coherent regulatory framework. Urge EPA to not finalize guidance until USDA Farm Bill process is done, and encourages EPA to work with states to not unnecessarily bring products that are already registered in the states into FIFRA's registration process. They appreciate Tables 1-3 but are concerned that they may be utilized to bring products which have fertilizer/biostim impacts on plants and soil under FIFRA. Also suggest EPA work with states to determine best approach on dual-use products. Want EPA to work with states to not bring thing over unnecessarily, say some of the claims in Table 3 conflict with state laws.

"enhance/promote/stimulate plant growth and development" and "enhance/promote fruit growth and devel" are examples - say some state lawns define fertilizers as substances with nutrients that promote or stimulate plant growth. Also say table 4 is a departure from the intent and could conflict with state law - it includes lots of ingredients already regulated as fertilizers by states.

KSE	Ex. 5 Deliberative Process (DP)	remove
HSESi		revise or remove

0078	G. Orr, Verdesian Life Sciences LLC	Industry/Trade Group/Grower/Farmer
0164	Humic Products Trade Assn et al on behalf of M. Turner, Catalyst Product Group	Industry/Trade Group/Grower/Farmer
0068	L. Rea, Sipcam Agro USA	Industry/Trade Group/Grower/Farmer
0011	J. Lilly, BASF	Industry/Trade Group/Grower/Farmer
0021	T. Stone, Agrinos, Inc	Industry/Trade Group/Grower/Farmer
0019	A. Plato Roberts, Danstar Ferment AG-Lallemand Plant Care	Industry/Trade Group/Grower/Farmer

Concerned that EPA definition of PGR is overreaching and will encompass many/all products fitting PBS definition. Say states are already basing decisions on the DG. Suggest that tables 1-3 be footnoted to remind user that guidance is nonbinding and to say list of claims is not exhaustive. Have issues with EPA's description of what a PBS is: say definition is about substance not product while FIFRA is a labeling law based around product's purpose (they talk about dual-use scenarios), say it shouldn't be limited to naturally occurring Als, conflates definition of soil amendment and PBS (soil amendment definition says ...intended for purpose of improving soil characteristics favorable for plant growth, so there's overlap), mentions that natural processes stimulated by PBS are physiological in nature, saying it will push all PBS in PGR category (so should try to clarify what that means in document..), fails to explicitly state that increases in crop qual/yield are stated objectives in farm bill PBS definition provided for mandated USDA report to congress. Say inclusion of Table 4 is problematic, want it removed, but also provide some specific edits: corn gluten meal is FIFRA 25(b) pesticide exempted from reg, micronutrient salts of humic substances are recognized nutriend source, including with foliar application, SE can elicit responses akin to auxins, cytokinins, gibberellins but the extracts do not contain signif levels of these hormones, AAs are source of nitrogen, Silicates are plant nutrients... Want PBS definition/description to say soemthing like "a nutritional chemical product consisting of a substance or substances that act to improve a plant's natural nutrition processes independent of the substance's nutrien content, thereby improving nutrient availability, uptake, or use efficiency, tolerance to abiotic stress, and subsequent growth, development, quality, or yield". Also want vitamin and hormone exemption extended to food crop uses.

Similar to 0080, 0060, 0152, 0162, 0061, 0073, 0071, 0059, 0064, 0076, 0054, but some additional documents. Mention stigma of EPA registration in organic community, say having to do EPA registration would ruin their business, they're only naturally doing what soil and plants naturally do. Think all products with HFSE would need to be registered. Say they're just trying to make healthy soil, add organic content. Want alignment with USDA definition of PBS in report to congress, want EPA to wait for that. Say design of table 4 is divergent from claims-based outline of DG. Also mention CPPA/H issue, lack of clarity of materials.

Similar to 0080, 0060, 0152, 0162, 0061, 0073, 0071, 0059, 0064, 0076, 0054, 0164

extension request

extension request

extension request

0081	M. Brooks, Ag-Chem Consulting on behalf of Plant Health Intermed	Industry/Trade Group/Grower/Farmer
0062	K. Bishop, Lebanon Seaboard Corp	Industry/Trade Group/Grower/Farmer

Want increased clarity from EPA on types of product label claims that amount to PR claims and development of definition of PBS. Want more comprehensive guidance, especially with respect to what is a pesticide/PR and what is an exempt plant nutrient, vitamin hormone product, or something in between but also exempt. Say since congress intended to exempt many PBS from FIFRA regulation, EPA should develop its own definition of PBS, including to make it clear that many/most naturally-occurring PBS are exempt because they are intended for use as something other than PGR. Line between PGR and fertilizer needs to be clearer, highlight the FIFRA definition of PGR excluding substances to that extend that are intended as plant nutrients etc. Say the 2018 Farm Bill definition of PBS is basically fertilizer definition. Want agency to develop its own independent definition. Say DG fails to provide clear, comprehensive guidance on full scope of PGR claims, Als that subject products to FIFRA reg: can products exempted as vit-horm still make PGR claims? 25(b) products make pesticidal claims bc they're exempt from registration, so vit-horm should be able to make PGR claims. Don't like that table 3 is not comprehensive - want it more explicit. Also, want to know about products that contain Als from Table 4 but do NOT make PR claims. Say DG makes no connection between label claims and Als - want that explicitly clear. Request a 2 year grace period in registrations/label revisions.

Split comments into 3 groups. 1. Tables 1-3 amendments: lists are too narrow in scope, concerned that regulatory agencies will limit to those claims. Have line by line changes including adding seed nutrition/foliar nutrition, improved nutrient uptake, expand to more phenotype changes, some additional claims they want included. Say many table 3 claims are too broad, apply to nutrients, inoculants, soil amendments, etc. Want "beyond innate genetic potential" addressed. 2. Table 4 and associated text removed since it introduces substance-based criteria, since they say it indicates that products containing ingredients in Table 4 require registration when many have not, historically. 3. Products excluded from regulation as PRs: Nutritional Chemicals. EPA didn't define nutritional chemicals, say other nutritional-based chemicals that aid in growth of desirable plants should be excluded from regulation as PRs. Say lots of PBS call into this, like AAs, organic extracts. Want EPA to define all statutory exclusions, including nutritional chemicals. They suggest a definition for it: a substance or substances that act to improve a plant's natural nutrition processes independent of the substance's nutrient content, thereby improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and subsequent growth, development, quality or yield.

Ex. 5 Deliberative Process (DP)

remove

0167	A. Prichard, CA Dept of Pesticide Regulation	US State
0154	R. Taylor, Humic Products Trade Assoc	Industry/Trade Group/Grower/Farmer
0034	T. Stopyra, Certified Crop Advisor	Industry/Trade Group/Grower/Farmer
0096	Anonymous	Private Citizen
Counts:	<i>Industry/Trade Group/Grower/Farmer</i>	85
	<i>Private Citizen</i>	69
	<i>US State</i>	4
	<i>State Association of Regulatory Officials</i>	2
	<i>Non-US Trade Association</i>	1
	Extension Request	18

DPR wants EPA to develop a PBS definition, which will help in making determinations whether products require registration and provide distinction between what is regulated and what is excluded. DPR suggests descriptors in Table 3 to include "vigorous growth", "encourages growth", "earlier maturation", and some others. To table 4, they suggest addition of variations of term SE like concentrated seaweed, derived from kelp, algae of the sea, etc. Wants to know if list will be updated as new AIs are registered. Bring up cytokinins and gibberellins - say that on p10 it says that Table 4 lists things that have MOA and associated label claims that trigger registration, ut label review manual says cytokinins and gibberellins trigger registration without claim since they have no use other than as PGR. Is EPA changing this? Request clarity on some specific claims and whether they'd be PGR claims or not: "is a plant and soil vitality booster featuring a natural blend of cold processed seaweed that encourages thriving growth of roots, stems, and foliage", "these fungi build a natural microbial system in and on plant roots which greatly enhance plant growth and vigor", "is a carefully selected blend of natural and organic fertilizers formulated to encourage multiple blooms and seed formation"

Want EPA to wait and work with USDA on definition for PBS. Say Table 4 doesn't appear to be claims-based - want it removed. Disagree with proposed language to restrict foliar-applied HF, bring up composition/identity of CPPA in table. Talk about their endorsed test methodology. Lots of overlap with other comments. Say humic substances have significant commercial value for non-pesticidal uses (soil improvement uses), want nutritional chemicals to be defined.

Question what makes a bona fide PGR - mention that lots of claims aren't validated, some come from testimonials. Mention long history of use of SE, derivatives like salicylic acid without oversight. Say lists in document (especially Table 4) are incomplete and will generate confusion. Footnotes fail to adequately define what are naturally occurring PGRs given that some may be artificially synthesized. Talk about the effects happening at concentrations below what would be needed to be used as a nutrient (ie HFSE applied at much higher concentrations than ABA, GABA, harpins, ets).

Not beneficial to try to re-classify PBS as pesticides. Say HFKSi are often fully organic, free of pesticides, say "if this law is passed" it will prevent organic growers from labeling their produce as organic.

H:

F:

K:

SE:

Si:

sum

161

Submitter Type	
Industry/Trade Group/Grower/Farmer	70
Private Citizen	84
US State	3
State Association of Regulatory Officials	2
Non-US Trade Association	1

File Number	Submitter	Submitter Category
0006	Anonymous	Private Citizen
0007	Anonymous	Private Citizen
0008	Anonymous (but they make comments that sound like they're industry-related, ie "our internal report", "industry questions why EPA...")	Industry/Trade Group/Grower/Farmer
0009	R. and S. Ellis	Industry/Trade Group/Grower/Farmer
0010	B. Planques, Italtapollina USA Inc	Industry/Trade Group/Grower/Farmer
0011	J. Lilly, BASF	Industry/Trade Group/Grower/Farmer
0012	D. Pearce, Pathway BioLogic	Industry/Trade Group/Grower/Farmer
0013	R. Taylor, Humic Products Trade Assoc	Industry/Trade Group/Grower/Farmer
0014	E. Scott, Actagro	Industry/Trade Group/Grower/Farmer
0015	K. Jones, Biological Products Industry Alliance	Industry/Trade Group/Grower/Farmer

Comment summary

No products like these should be used until "us dept of health" investigated the effects of eating plants grown with this new product, say this is using Americans as guinea pigs, say USDA is out for profiteering, doesn't care who dies as a result

Praise the guidance but write about abiotic stressors impacting fruit yield/size, and say reducing abiotic stress is exempt but fruit yield/size isn't, so this should be exempt since it is due to abiotic stress reduction.

Say guidance does a good job explaining what compounds should and shouldn't get regulated as pesticides, except for HF, tannins, organic acids from leonardite, since they're part of a normal plant living environment. They shouldn't be in table 4. Say approx 50% of carbon in soil is sequestered in stable forms of humic substances, say regulating these substances would have no impact on human exposure to them, discuss some methodology for measuring fulvic acid components. They mention the current rule at 7 CFR 205.203(d)(2) states that humic and fulvic acids must come from a mined mineral, but they believe that isn't being followed in all cases. Industry questions why EPA is listing humic and fulvic acids in same grouping at CPPA, say there are data showing they behave differently and humic substances shouldn't be regulated as pesticides. Say table 4 should be revised so it doesn't encompass a majority of earth's humus and instead list specific known active compounds without HF, tanins, organic acids from leonardite.

their product is not a pesticide but would be treated as one under the guidance. All ingredients are organic and/or food ingredients, labeling as a pesticide will require them to locate another formulator/packager

extension request

extension request

extension request

extension request

extension request

extension request

0016	D. Beaudreau, US Biostimulant Coalition	Industry/Trade Group/Grower/Farmer
0017	R. McDonald, BioLiNE	Industry/Trade Group/Grower/Farmer
0018	P. Perez, PlantResponse Biotech	Industry/Trade Group/Grower/Farmer
0019	A. Plato Roberts, Danstar Ferment AG-Lallemand Plant Care	Industry/Trade Group/Grower/Farmer
0020	S. Lebo, Sustainable AGRO Solutions, LignoTech USA	Industry/Trade Group/Grower/Farmer
0021	T. Stone, Agrinos, Inc	Industry/Trade Group/Grower/Farmer
0022	Catherine Bishop, Lebanon Seaboard Corp	Industry/Trade Group/Grower/Farmer
0023	S. Van Wert, Bayer CropScience	Industry/Trade Group/Grower/Farmer
0024	C. Mamone, Indigo Agriculture	Industry/Trade Group/Grower/Farmer
0025	M. Key, Impello Biosciences	Industry/Trade Group/Grower/Farmer
0026	Anonmyous (commercial plant grower)	Industry/Trade Group/Grower/Farmer
0027	M. Siddoway, BioSaphe	Industry/Trade Group/Grower/Farmer
0028	Y. Fuentes, BioSafe Systems	Industry/Trade Group/Grower/Farmer
0030	J. Ott, Nevada Dept of Ag	US State

extension request
extension request
Want seaweed extracts and kelp to be considered fertilizers, excluded from FIFRA requirements, cite long history of safe use, registration as fertilizer in states, etc.
extension request
extension request
extension request
extension request
extension request
extension request
extension request
extension request
Commercial plant grower, thinks like of these biostimulants that aren't labeled or registered as pesticides or fertilizers, don't know what's in them, but think what makes them beneficial would be identical to other items registered as pesticide or fertilizer. Thinks EPA should require the registrant to show how product works and what AI is, then determine if AI is a pesticide or a fertilizer.
extension request
extension request
Want clearer definition of PBS - note that there are apparent discrepancies between 2018 Farm Bill definition and EPA's description in the DG, specifically noting that farm bill seems to have one overall category but EPA splits it into pesticidal and non-pesticidal. They note that both non-pesticidal product labels and those that trigger regulation under FIFRA has synonymous descriptors that also appear in the farm bill definition.

	Ex. 5 Deliberative Process (DP)	

0031	T. Stopyra, Intl Agribusiness Consultants	Industry/Trade Group/Grower/Farmer
0032	J. MacKay, Cool Planet Energy Systems	Industry/Trade Group/Grower/Farmer
0033	Anonymous (Commercial scale produce grower)	Industry/Trade Group/Grower/Farmer
0034	T. Stopyra, Certified Crop Advisor	Industry/Trade Group/Grower/Farmer
0035	R. Welsh, Law Office of R. Welsh	Industry/Trade Group/Grower/Farmer
0036	Anonymous (work with pesticide and fertilizer registrants)	Industry/Trade Group/Grower/Farmer
0037	D. Vanderhoff, Chamberlin Ag	Industry/Trade Group/Grower/Farmer

Main problem is defining what constitutes a PGR - say random testimonials aren't sufficient as basis of claim. Use of seaweeds goes back centuries. Say Table 4 is incomplete, will generate confusion among prospective registrants - footnotes fail to adequately define what are naturally occurring PGRs given that some must be artificially synthesized. Think addition of info on rate/quantity required for effect, as PGRs should act at lower levels than nutrients. Say including long list of PBS as PGR will create confusion, economic hardship. Says EPA is probably ill-prepared to receive dozens of applications for these and to respond in timely manner. Say full impact won't be known until EPA implements the guidance.

extension request

They use biostims, strongly oppose regulation of biostims, say there is nothing harmful, and it's the harmful nature of pesticides that requires regulation, some are very effective and increase growth at least 10%, worried some will be taken off market or go up in price. Also say biostims are totally different from PGRs, which are unnatural and highly developed to imitate nature. PGRs should be regulated, but biostims shouldn't.

Question what makes a bona fide PGR - mention that lots of claims aren't validated, some come from testimonials. Mention long history of use of SE, derivatives like salicylic acid without oversight. Say lists in document (especially Table 4) are incomplete and will generate confusion. Footnotes fail to adequately define what are naturally occurring PGRs given that some may be artificially synthesized. Talk about the effects happening at concentrations below what would be needed to be used as a nutrient (ie HFSE applied at much higher concentrations than ABA, GABA, harpins, etc).

Want streamlined process, ideally exempting PBS from registration. Mention confusion from some of the issues (ie how is "improves nutrient assimilation" different from "enhances fruit growth and development" since presumably one could lead to the other)

Believes EPA shouldn't regulate PBS or growth regulators, shouldn't have ever been called pesticides, FIFRA should revise/remove sections 2(u) and 2(v), say even by the definition they're not sure why EPA is regulating as pesticides, EPA and FIFRA should focus on chemical pesticides, or EPA needs shortcut way to registration for these, EPA is backed up, etc.

PBS aren't PGR and therefore aren't pesticides and shouldn't be subject to FIFRA. Products will be inhibited, reducing farmers' ability to increase sustainability and productivity, USDA already wrote definition of PBS, think that EPA wants to use rulemaking to make PBS subject to FIFRA, reference label review manual with regard to claims-based approach, note that PGR needs to go beyond "simple plant nutrition" which is not defined.

HFSE		
	Ex. 5 Deliberative Process (DP)	
HSE		revise

0038	Anonymous	Private Citizen
0039	Nancy Burke, Saul Ewing Arnstein & Lehr on behalf of Pioneer Peat, Inc.	Industry/Trade Group/Grower/Farmer
0040	L. Mayhew	Private Citizen
0041	BioAtlantis	Industry/Trade Group/Grower/Farmer

Say seaweeds themselves are not AIs, though some seaweed-based products are registered as plant regulators, say there's a concern with listing SE in Table 4. Specifically call out the lack of chemical characterization, identification of multiple MOA, whether or not the biostimulant/growth regulator claims are adequate. Concerns are explained in more detail, but highlights: definition of SE is not verifiable due to diversity of seaweeds, not all have bioactive response when applied to plants, their complexity makes it difficult to ascribe plant responses to specific regulators, gives some example MOAs, say SE shouldn't be assumed to have a unique MOA similar to registered plant regulators. Finally, say the effects of SE are better represented by claims that are not regulator claims, better first nutrition-based claimed or non-pesticidal claims. Want consistent biostim definition to what is used by USDA in report to congress.

Commenting on behalf of a company that produces and sells natural soil amendments for improvement, maintenance, survival, etc of plants. They oppose the guidance saying it unreasonably limits the claims that producers may make for their products, ignoring the full import of the statutory exceptions to the definition of plant regulator. Under FIFRA 2(v), is says plant regulator shall not include substances intended as plant nutrients, trace elements, nutritional chems, plant inoculants, soil amendments and also shall not be required to include any of the nutrient mixtures/soil amendments commonly known as vitamin-hormone horticultural products. They want producers to be able to make such claims about their products - concerned about products being unfairly limited in their claims because improving plant health will also promote plant growth/development. Also says humic acids shouldn't be included since they're inherent to soil and peat. Also say this guidance captures exempt products and would "regulate plain old dirt as a pesticide". Say the guidance is designed to benefit large companies, discourage small businesses.

various substances are being called pesticides that shouldn't, and they think this guidance is a change in the framework.

Provided data saying seaweed extracts in their products aren't effective because of hormones, but instead it's just about abiotic stress reduction

SE		revise
	Ex. 5 Deliberative Process (DP)	
H		
HFSE		
SE		

0042	P. Miars, Organic Materials Review Institute	Industry/Trade Group/Grower/Farmer
0043	Anonymous (rancher)	Industry/Trade Group/Grower/Farmer
0044	Dave, Illinois	Private Citizen
0045	Anonymous	Private Citizen
0046	Anonymous	Private Citizen
0047	J. Vaughan	Industry/Trade Group/Grower/Farmer
0048	Anonymous (growing hemp)	Industry/Trade Group/Grower/Farmer
0049	Anonymous	Private Citizen
0050	Anonymous (distributor of products)	Industry/Trade Group/Grower/Farmer

Say the DG clarifies that PBS should be considered PGRs. Say name and executive summary suggest purpose of guidance is to help stakeholders identify pesticidal label claims, but DG expands beyond that when it says label claims alone are not the only criteria that should be used when identifying PGRs subject to registration as pesticides. The include suggested deletions and additions to executive summary for clarity. Suggested edits are addressed in doc. Want text introducing table 4 to change, say that the table impacts many of the products they list as crop fertilizer and soil amendment products. Say guidance could result in several hundred new registrations.

Think this is a rule, thinks it is a way for big corporations to bankrupt organic fertilizer movement

Opposed to classifying natural fertilizers as pesticide, thinks this changes regulatory approach, impacts small business. Call this "draft regulation", want it to be changed

Bad idea, will drive price of organic produce up, say this is attempt by traditional agribusiness lobby

HFSE are valuable soil additions, shouldn't be registered as pesticides, which will diminish their availability which is concerning to organic farmers, want organic products kept out of pesticide registration

Biostimulants shouldn't be pesticides, thinks this is evidence of chemical industry avoiding natural alternatives, thinks this is a change in regulation

Oppose regulation of organic materials (HFKSE) as pesticides,

Against listing KSE as pesticides that need registration

Think DG is a change in guidelines, making something a pesticide that was not before, want PBS to be clearly defined. Want free market or in separate category with little to no oversight. Say this will stifle innovation.

		revise
	Ex. 5 Deliberative Process (DP)	
HFSE		
HFKSE		
KSE		

0051	Anonymous	Private Citizen
0052	Anonymous (represents Lazy Gator's Hemp Farm)	Industry/Trade Group/Grower/Farmer
0053	Anonymous	Private Citizen
0054	L. Bunderson, Aqua-Yield Operations LLC	Industry/Trade Group/Grower/Farmer
0055	S. Lebo, Sustainable AGRO Solutions, LignoTech USA	Industry/Trade Group/Grower/Farmer
0056	H. Dramm, Dramm Corporation	Industry/Trade Group/Grower/Farmer

Say confusion arises because of inclusion of SE in table 4, as there are many types of SE with diff chemical compositions and no universally accepted MOA. Mention the varying concentrations of things like auxins, cytokinins, gibberellins, and the fact that SE also contain carbohydrates, trace elements, AAs, vitamins, nutrients, etc, all of which vary based on source/timing of harvest, and there's no clear understanding of what component plays what role on plant health. Therefore it isn't appropriate for EPA to consider all SE subject to FIFRA on MOA basis. Mention that DG says PBS are relatively new, but SE have been used for centuries. Mention that many effects of SE could be considered non-pesticidal. Say SE have been considered plant nutrients for years. Mention what other commenters have said, including that it's not clear if the benefits of using SE are from the presence of phytohormones that appear to be triggering PGR consideration. Want SE out of table 4. Also say SE should be added to minimum risk pesticides.

Want table 4 out, don't think HFKSE should be pesticides, say the ingredients are all NOP compliant, but this will increase the cost of fertilizers etc

SE should be exempt because they're not pesticides, labeling them as such may prohibit their use by organic gardeners, industry impacts, gave some history of seaweed use, just because it's a biostimulant doesn't mean it needs to be regulated, thinks this traces back to chemical fertilizer industry, says these are vegetable extracts not pesticide

Similar to 0080, 0060, 0152, 0162, 0061, 0073, 0071, 0059, 0064, 0076

Letter appears to have been drafted by Humic Products Trade Assoc. Want definition of PBS as presented in 2018 Farm Bill to be clarified, and EPA wants to align with the definition in the USDA report to Congress, says EPA should wait before finalizing. Mentions history of why some would want to get FIFRA registration to satisfy complicated state registrations. They have specific expertise in HF, listed in Table 4. They agree that soil amendment exemptions for soil-applied HFs should be maintained, but disagree with the proposed language in draft that restricts foliar-applied HF. Say compositional differences should be considered, bring up use of CPPA category, discrepancies in what may actually be registered vs other products. Say guidance doesn't consider the exemptions at 152.15a-c, regarding other commercially valuable uses. Say Humic substances are used for non-pesticidal uses with significant commercial value. They say there will be added burden as a result of guidance even though EPA says otherwise.

Sell liquid fertilizers to organic market, and several of the blends include HFSE. They're opposed to including those as pesticides - say using these substances as generic raw materials shouldn't trigger oversight. Want guidance to focus on product claims, not meterly presence of these ingredients. Very similar to earlier comment (0079)... say as long as no pesticidal claims, shouldn't need to be registered. Want table 4 either revised or removed. Also want clear definition of PBS. Specific questions: does amount of plant regulator make a difference? At what volume, weight, or concen is a PR effective? How will EPA coordinate with States, NOP, or AAPFCO requirements? When will EPA or appropriate agency define PBS?

	Ex. 5 Deliberative Process (DP)	
SE		revise
HFKSE		remove
SE		
		remove
HF		remove
HFSE		revise or remove

0057	P. Syltie, Vital Earth Resources	Industry/Trade Group/Grower/Farmer
0058	J. Wilson, Atlantic Laboratories, Inc	Industry/Trade Group/Grower/Farmer
0059	R. McDonald, BioLiNE	Industry/Trade Group/Grower/Farmer
0060	J. Breen, Actagro	Industry/Trade Group/Grower/Farmer
0061	K. Pitts, Marrone Bio Innovations	Industry/Trade Group/Grower/Farmer
0062	K. Bishop, Lebanon Seaboard Corp	Industry/Trade Group/Grower/Farmer

Biostimulants shouldn't be pesticides, thinks this is a change in regulation, want them to be freely marketed as non-toxic or in a separate category with little to no oversight.

Want label claims considered, say HFSE should be able to be used in fertilizer without pesticide claim, will have economic implications, think this is change in framework (say current is good enough, but what the guidance describes is bad), want table 4 deleted or revised to remove HFSE

Similar to 0080, 0060, 0152, 0162, 0061, 0073, 0071

Comments in 5 categories: ongoing regulatory uncertainty, impacts on innovation, economic implications, market access for PBS products, and accessibility for end users. Ongoing reg uncertainty included claims-based regulation - significant overlap/shared language with -0080. As alternate to deleting table 4, suggest language saying that although these substances have been selected for FIFRA reg by some companies, they may not be required to be registered depending on the conditions described in FIFRA and lines 101-105 of the guidance. Also mention potential conflicts with other federal efforts like USDA report to congress and quantify some of their estimated economic impacts if the guidance is implemented as written.

Similar to 0080, 0060, 0152, 0162.

Split comments into 3 groups. 1. Tables 1-3 amendments: lists are too narrow in scope, concerned that regulatory agencies will limit to those claims. Have line by line changes including adding seed nutrition/foliar nutrition, improved nutrient uptake, expand to more phenotype changes, some additional claims they want included. Say many table 3 claims are too broad, apply to nutrients, inoculants, soil amendments, etc. Want "beyond innate genetic potential" addressed. 2. Table 4 and associated text removed since it introduces substance-based criteria, since they say it indicates that products containing ingredients in Table 4 require registration when many have not, historically. 3. Products excluded from regulation as PRs: Nutritional Chemicals. EPA didn't define nutritional chemicals, say other nutritional-based chemicals that aid in growth of desirable plants should be excluded from regulation as PRs. Say lots of PBS call into this, like AAs, organic extracts. Want EPA to define all statutory exclusions, including nutritional chemicals. They suggest a definition for it: a substance or substances that act to improve a plant's natural nutrition processes independent of the substance's nutrient content, thereby improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and subsequent growth, development, quality or yield.

HFSE		remove
HF		remove
	Ex. 5 Deliberative Process (DP)	remove
HF		remove
		remove

0063	D. Middleton, Ocean Organics Corporation	Industry/Trade Group/Grower/Farmer
0064	Agricultural Retailers Association et al.	Industry/Trade Group/Grower/Farmer
0065	G. de la Borda, Stoller Enterprises	Industry/Trade Group/Grower/Farmer
0066	D. Woods, CA Dept of Food & Ag	US State
0067	M. Menes, True Organic Products, Inc.	Industry/Trade Group/Grower/Farmer
0068	L. Rea, Sipcam Agro USA	Industry/Trade Group/Grower/Farmer
0069	P. Barbera, Shoreside Organics	Industry/Trade Group/Grower/Farmer
0070	L. Bonini, European Biostimulants Industry Council	Non-US Trade Association

Support other comments, and say they have a few points of their own. Say Table 4 goes beyond being claims-based and is inappropriate, too far-reaching. Would damage their company because they use HFSE in non-pesticidal ways. Say SE support natural plant nutrition processes, saying their role isn't as PR. They mention concentration issues and that PRs are meant to be pure and used at specific concentrations.

Similar to 0080, 0060, 0152, 0162, 0061, 0073, 0071, 0059, but include economic impact appendix.

Want clarified that tables 1-3 aren't comprehensive. Table 4 appears to trigger registration, and they support the table and in particular the inclusion of SE, which they acknowledge is a complicated case as there are cases where it was used in products described as fertilizers or vit-hormone products. Want EPA to review the USDA report to congress for PBS definition and then incorporate based on that. Say there will be economic benefits from DG because of clarity provided to states, producers, growers, etc.

Note that some label claims in guidance appear to be interpreted differently by CDFA and EPA. Mention the Fertilizing Materials Inspection Branch which oversees and enforces regulations related to fertilizing materials. They note areas of disagreement, like Table 3: some of the examples go beyond pesticide action, like enhances/promotes/stimulates plant growth and dev or fruit growth and dev, which overlaps with CDFA's definition of commercial fertilizer, Table 4 includes ingredients in widespread use in foliar fertilizing material products (list SE, H, Si). Want to know if products like SE and H are a priori pesticides or if it depends on label claims. They don't think EPA needs to define biostimulant at this point.

Say HFSE inclusion in Table 4/as Als that need registration as pesticides is inappropriate because the generic raw materials are subject to FIFRA if pesticidal claims are made, and they say the guidance should focus on the claims. Registration of all products containing HFSE will have immediate negative impact on their fertilizer products. They do indicate that the guidance is a change in regulatory structure and registration requirements. They suggest removing Table 4 and focusing on the claims as opposed to the individual materials.

Similar to 0080, 0060, 0152, 0162, 0061, 0073, 0071, 0059, 0064, 0076, 0054, 0164

Opposes guidance to regulate some organic materials as pesticides, will be costly for what is naturally occurring, this is overregulation

Similar to some others. Broad topics: guidance should respect claims-based approach, economic implications could inhibit innovation, and finalization should be delayed to allow for coordination with USDA on relevant aspects of Ag Improvement Act of 2018. Want it spelled out that the tables 1-3 aren't comprehensive. Table 4 should be removed because of claims-based issues and confusion. Think changes from the guidance could hurt the R&D of PBS and other innovation. Want EPA to wait to finalize.

HFSE	Ex. 5 Deliberative Process (DP)	remove
		remove
HSESi		
HFSE		remove
		remove
HSE		remove

0071	M. Fraley, Seawin USA, Inc	Industry/Trade Group/Grower/Farmer
0072	S. Van Wert, Bayer CropScience	Industry/Trade Group/Grower/Farmer
0073	D. Benmhend, FMC Corporation	Industry/Trade Group/Grower/Farmer
0074	E. Thomas, The Fertilizer Institute	Industry/Trade Group/Grower/Farmer

Similar to 0080, 0060, 0152, 0162, 0061, 0073

Want EPA to wait and work with USDA on definition for PBS. Want language added to make it clear that tables 1-3 aren't comprehensive, which was done. Want better clarify on what is a PR and what's excluded under FIFRA. Want table 4 removed. Suggest decision tree be added. List specific changes, line by line, including removal of "naturally occurring" as it's undefined and could limit future innovation/technology advancements, say diff definitions of PBS occur at lines 48-50 and 75-79, want EU fertilizers definition included for PBS, note other inconsistencies about plant growth (ie growth of whole plant is fine but of specific parts isn't), want guidance to address situations where there are multiple MOA and some fall outside FIFRA, say "enhances plant growth and development" as PR claim is too broad since it also applies to nutrients, inoculents, soil amendments, want term deleted from table 3. Also stand by BPIA and BC comments.

Similar to 0080, 0060, 0152, 0162, 0061. Say other countries are leading the way with progressive regulations for PBS, while EPA's additional regulations will be burdensome and make technologies less available. Also suggest regulatory harmonization to facilitate trade.

TFI represents fertilizer industry, and PBS are routinely blended with fertilizers or retailed as supplemental products. TFI is concerned that, as written, the guidance imposes requirements that go beyond the intent of FIFRA. Say PBS aren't plant regulators (or fertilizers). 1. want table 4 removed - say claims-based approach is reasonable and including which claims are and aren't PGR makes sense, but then table 4 lists substances regardless of claim - say it's deviation from claims-based approach. Concerned about misinterpretation of table 4 - say it is oversimplification of the actual requirements of the law. 2. want clarification on FIFRA exclusion provisions (re: plant nutrients, trace elements, nutritional chems, plant inoculants, soil amendments). They say PBS' are innovative products that Congress envisioned when crafting FIFRA and thought they'd go in plant inoculant/nutritional chem categories and want clarification on the intent of Congress' use of the term nutritional chemicals (and say that non-microbial PBS generally meet nutritional chem exclusion - they also offer an interpretive definition). 3. consult with USDA. Don't define PBS until USDA and stakeholders (with EPA) work together to develop one. Don't want EPA to finalize guidance yet.

HF	Ex. 5 Deliberative Process (DP)	remove
		remove
HF		remove
		remove

0075	K. Davis, WA State Dept of Ag	US State
0076	L. Bunderson, Aqua-Yield Operations LLC	Industry/Trade Group/Grower/Farmer
0077	J. Sooby, CCOF	Industry/Trade Group/Grower/Farmer

Say guidance will be useful to State staff regulating pesticides and fertilizers. Say table 4 is one of the most valuable parts as it makes clear that certain ingredients are pesticides and should be regulated as such. Some line by line comments, including that the guidance doesn't cover all types of PBS like some Bacillus strains - want adding "or biopesticides" after "plant regulators". Want us to wait to develop PBS definition, point out that PBS aren't new and reference 1993 registered product calls a biostimulant. Say not all PBS are natural so that should be removed from EPA's description - they provide some suggested edits/additions. Want it clearly stated that biostimulant is, not by itself, a pesticide claim - want additional clarity. Want MOA considered in addition to label claims, say many PBS products include claims for secondary effect that aren't pesticidal, but MOA of product is as pesticide (example: hormone to increase root growth by MOA, but label claim is increased nutrient uptake). Table 1a - "soil" in several bullets should be removed from 1a and moved to 1c. Request clarification around what "behaviors" are included as physiological actions. Promotion of plant growth can be a nutrient/fertilizer claim. Table 4 question - do the ingredients need to be associated with pesticide claims on label/labeling to be considered pesticide? Lots of table 4 comments regarding clarification (but say it needs to stay).

Similar to 0080, 0060, 0152, 0162, 0061, 0073, 0071, 0059, 0064

Org advocates for organic policies. Think this guidance will result in certified organic producers losing access to important tools with decades of safe use. Want HFSE removed from table 4 since they're listed as ingredients that are required to be registered as pesticides - says they're proposed to be classified as PGRs. They agree that the products that contain these and are specifically formulated and labeled for PGR use should be regulated as pesticides, but when just used as foliar nutrients or delivery matrix to carry nutrients, which shouldn't be classified as pesticides. Organic fertilizers containing these substances are currently exempt, and they say they should continue to be exempt. Say organic farming is already well-regulated under USDA's NOP.

		Ex. 5 Deliberative Process (DP)	
HFSESi			
			remove
HFSE			revise

0078	G. Orr, Verdesian Life Sciences LLC	Industry/Trade Group/Grower/Farmer
0079	E. Chandler, Thorvin, Inc	Industry/Trade Group/Grower/Farmer
0080	D. Hiltz, Acadian Seaplants	Industry/Trade Group/Grower/Farmer

Concerned that EPA definition of PGR is overreaching and will encompass many/all products fitting PBS definition. Say states are already basing decisions on the DG. Suggest that tables 1-3 be footnoted to remind user that guidance is nonbinding and to say list of claims is not exhaustive. Have issues with EPA's description of what a PBS is: say definition is about substance not product while FIFRA is a labeling law based around product's purpose (they talk about dual-use scenarios), say it shouldn't be limited to naturally occurring AIs, conflates definition of soil amendment and PBS (soil amendment definition says ...intended for purpose of improving soil characteristics favorable for plant growth, so there's overlap), mentions that natural processes stimulated by PBS are physiological in nature, saying it will push all PBS in PGR category (so should try to clarify what that means in document..), fails to explicitly state that increases in crop qual/yield are stated objectives in farm bill PBS definition provided for mandated USDA report to congress. Say inclusion of Table 4 is problematic, want it removed, but also provide some specific edits: corn gluten meal is FIFRA 25(b) pesticide exempted from reg, micronutrient salts of humic substances are recognized nutrient source, including with foliar application, SE can elicit responses akin to auxins, cytokinins, gibberellins but the extracts do not contain signif levels of these hormones, AAs are source of nitrogen, Silicates are plant nutrients... Want PBS definition/description to say something like "a nutritional chemical product consisting of a substance or substances that act to improve a plant's natural nutrition processes independent of the substance's nutrient content, thereby improving nutrient availability, uptake, or use efficiency, tolerance to abiotic stress, and subsequent growth, development, quality, or yield". Also want vitamin and hormone exemption extended to food crop uses.

HFSE as generic raw materials should not trigger registration as pesticides. They're frequently used as fertilizer ingredients. Should only be subject to FIFRA if pesticidal claims are made. The guidance should focus on claims.

Fully support comments submitted by BPIA and USBC, also members of EBIC and have worked for years to define new regulatory environment for PBS in EU. Thinks that as written, this guidance may create more confusion, concerned that state regulatory agencies, industry, and other stakeholders will keep having questions about how PBS should be registered. Point of Table 4 with mention of HSE would have huge regulatory burden. Want more clarity around definition of plant regulator, guidance should include claims-based approach, implied classification of certain well-established PBS as pesticides is not aligned with global regulation, and economic impact would be high. Detailed the requests more in letter - call out that growth regulator needs to alter/modify growth habit in a way that it would not normally behave under optimal growing conditions, and say PBS are neither intended nor claimed to alter/modify normal growth habits. Want clear PBS definition. Say Table 4 introduces substance-based criteria in addition to claims-based, and it is oversimplified. Mention that many table 4 registrations are very old, were useful at that time for national consistency. Want "nutritional chemical" both defined and excluded from PGR definition.

0081	M. Brooks, Ag-Chem Consulting on behalf of Plant Health Intermed	Industry/Trade Group/Grower/Farmer
0082	Anonymous	Private Citizen
0083	B. Wolf, Wolf, DiMatteo + Associates	Industry/Trade Group/Grower/Farmer
0084	K. Dodd	Private Citizen
0085	Advanced Nutrients US LLC (coded as Anonymous)	Industry/Trade Group/Grower/Farmer
0086	Anonymous	Private Citizen
0087	Anonymous	Private Citizen

Want increased clarity from EPA on types of product label claims that amount to PR claims and development of definition of PBS. Want more comprehensive guidance, especially with respect to what is a pesticide/PR and what is an exempt plant nutrient, vitamin hormone product, or something in between but also exempt. Say since congress intended to exempt many PBS from FIFRA regulation, EPA should develop its own definition of PBS, including to make it clear that many/most naturally-occurring PBS are exempt because they are intended for use as something other than PGR. Line between PGR and fertilizer needs to be clearer, highlight the FIFRA definition of PGR excluding substances to that extend that are intended as plant nutrients etc. Say the 2018 Farm Bill definition of PBS is basically fertilizer definition. Want agency to develop its own independent definition. Say DG fails to provide clear, comprehensive guidance on full scope of PGR claims, Als that subject products to FIFRA reg: can products exempted as vit-horm still make PGR claims? 25(b) products make pesticidal claims bc they're exempt from registration, so vit-horm should be able to make PGR claims. Don't like that table 3 is not comprehensive - want it more explicit. Also, want to know about products that contain Als from Table 4 but do NOT make PR claims. Say DG makes no connection between label claims and Als - want that explicitly clear. Request a 2 year grace period in registrations/label revisions.

Table 4 substances should be exempt. Don't push plant beyond what it can innately do. Small business impacts, too much to label, etc.

Involved in organic ag for over 30 years, see no issues with proper use of HFSE, want either generic materials (HFSE) removed from table 4 or table 4 deleted. Similar to 0056 and 0079. Say these generic raw materials are often used in fertilizers without pesticidal claims, guidance should focus on product claims, not the inclusion of specific substances. Say products containing these that DO make PGR claims should be registered as pesticides, but others shouldn't.

Want seaweed extracts and kelp to be considered fertilizers, excluded from FIFRA requirements, cite long history of safe use, registration as fertilizer in states, etc.

HFKSE shouldn't be registered as pesticides unless label claims are made, shouldn't be on Table 4 specifically identified as plant regulators subject to FIFRA. Also oppose Bt as pesticide ingredient unless pesticide label claims are made, as the microbe is recognized as an ingredient under fertilizer regulatory oversight and should stay there, not FIFRA

HFKSE aren't pesticides, this would hurt farmers

Do more research before banning such amazing products

HFKSESi	Ex. 5 Deliberative Process (DP)	
HFSE		revise or remove
KSE		
HFKSE		revise
HFKSE		

0088	Anonymous	Private Citizen
0089	Anonymous	Private Citizen
0090	Anonymous	Private Citizen
0091	Anonymous	Private Citizen
0092	Anonymous	Private Citizen
0093	Anonymous	Private Citizen
0094	Anonymous	Private Citizen
0095	Anonymous	Private Citizen
0096	Anonymous	Private Citizen
0097	Anonymous	Private Citizen
0098	Anonymous	Private Citizen
0099	Anonymous	Private Citizen
0100	Anonymous	Private Citizen
0101	Anonymous (refers to self as farmer)	Industry/Trade Group/Grower/Farmer
0102	Anonymous	Private Citizen
0103	Anonymous	Private Citizen
0104	Anonymous	Private Citizen
0105	Anonymous	
0106	Anonymous	Private Citizen

humic acid and silica aren't pesticides and EPA doesn't justify how they are. Do more research.
Kelp, silica, other biostim are not and shouldn't be regulated like pesticides
Think this is a change leading to these substances being pesticides, will harm small business
HK shouldn't be considered or used as pesticides, causes undue financial burdens, impacts products already on market, think this increases regulatory hurdles
HK are natural, EPA has no right to regulate, these shouldn't be considered pesticides
HK not pesticides, don't need to be regulated as such
These substances aren't pesticides, reclassification will hurt small businesses, and the guidelines should be re-evaluated
These aren't pesticides, this is money grabbing, etc
Not beneficial to try to re-classify PBS as pesticides. Say HFKSi are often fully organic, free of pesticides, say "if this law is passed" it will prevent organic growers from labeling their produce as organic.
Proposal is bad, classifying natural organic products as pesticides harms organic farmers/retailers, this is propaganda from big ag
HA and kelp shouldn't be pesticides, this is regulatory overreach
"This is ridiculous and not okay. Don't let this happen"
Thinks this is change in regulation, want it to be reconsidered, says we have enough regulation as is, and as long as "it is sustainably mined it should be ok"
Disagrees with "this claim", says biostims need to be studied more before the government classifies them as a pesticide, says "we (the farmers)" use these products more than anyone and know what they are truly capable of.
PBS aren't pesticides and shouldn't need to be regulated as such
See no reason to lump growth regulators that occur naturally within soil in with pesticides
"Keep it organic and natural"
Document too vague, no specifics as to what natural biostimulants are off topic, mention kelp and fulvic acid are sustainable, farmers can lose important tool, etc. Wants clearer definitions and for some of these natural things to not be treated as pesticides.
"This needs to be looked at more before just banning"

0107	Anonymous	Private Citizen
0108	Anonymous	Private Citizen
0109	Anonymous	Private Citizen
0110	Anonymous	Private Citizen
0111	Anonymous	Private Citizen
0112	Anonymous	Private Citizen
0113	Anonymous	Private Citizen
0114	Anonymous	Private Citizen
0115	Anonymous (kept as private citizen bc they say gardener, not farmer, but questionable given the cannabis reference?)	Private Citizen
0116	Anonymous (soil and crop consultant)	Industry/Trade Group/Grower/Farmer
0117	Anonymous	Private Citizen
0118	Anonymous	Private Citizen
0119	Anonymous	Private Citizen
0120	Anonymous	Private Citizen
0121	Anonymous	Private Citizen

Says this is all about money, EPA wants to regulate things that give life as pesticides, refer to this as new regulation

Many humics, kelp, silica products on market not intended for use as pesticides, will hurt market

"This is bull crap"

Against HK being regulated

Says this paints with broad brush, is short sighted, going to put small companies out of business because they won't have money to get through red tape

Want one good reason naturally-occurring biological additives should be grouped with pesticides, say whoever is benefitting/profitting off of this isn't the consumer

Guidelines are ludicrous because these products aren't pesticides, win for "big-ag" and GMO pushers"

Need more research, EPA is trying to regulate things we don't understand, will make things worse for people

HSE shouldn't be considered pesticides, they're an organic gardener and use kelp products, say they're normally already OMRI and NOP listed, think additional research needed, further discourse about what industries EPA is trying to regulate, and some of these products are in vegan soil mixes and favored by cannabis growers

PBS aren't toxic and don't act as pesticides, should not be considered pesticides, only form of regulation (if any) should be to assure toxins aren't combined with them, and if there are no toxins, they should be exempted from EPA regulations.

"-ide" means kill, these aren't pesticides

PBS aren't pesticides, don't have any of the same MOA, this regulation doesn't make sense, says this is EPA looking to create another barrier

Need more research, PBS play vital role in growing cannabis indoors.

Do more research, -ide means kill, these shouldn't be pesticides

PBS is broad category, think this focuses on HK, thinks this is based on chem-ag giants lobbying, say proposal is negligent.

0122	Anonymous	Private Citizen
0123	Anonymous	Private Citizen
0124	Anonymous	Private Citizen
0125	Anonymous	Private Citizen
0126	Anonymous	Private Citizen
0127	Anonymous	Private Citizen
0128	Anonymous	Private Citizen
0129	R. Hudak, Ag BioTech, Inc.	Industry/Trade Group/Grower/Farmer
0130	Anonymous	Private Citizen
0131	Anonymous	Private Citizen
0132	Anonymous	Private Citizen
0133	Anonymous	Private Citizen
0134	Anonymous	Private Citizen
0135	Anonymous	Private Citizen
0136	Anonymous	Private Citizen
0137	Anonymous	Private Citizen
0138	Anonymous	Private Citizen

HSE shouldn't be regulated as pesticides
These compounds aren't pesticides, are soil amendments, you'll harm farmers by regulating them.
More research should be done before H foliars are considered pesticides, they're not and aren't harmful
PBS aren't pesticides, agency should prioritize science, no evidence PBS are pesticides
HSE don't belong on table 4, more research needed.
Say more study is needed, they've used these substances for gardening for years and "test clean every single time", they aren't pesticides
HSE don't belong as pesticides, need more research
Wrong to classify PBS with other regulators and pesticides, especially as USDA NOP approves these for organic input. Mention methods through which the biostims work, say including them with pesticides is confusing, will have severe impacts on end users' choices, small business impacts, so PBS shouldn't be included in these "proposed regulations", should either be exempt from registration or in separate category without stringent oversight
Do more research, no need to rush to regulate biostimulants (like others, think this is regulatory change)
Minimum risk pesticide listing mentioned, mention high level of safety and efficiency
HSE don't belong in table 4 or as pesticides
These are nature, organic, shouldn't be labeled as pesticide, sad this is up for discussion
Please don't over-regulate environmentally-friendly products like HK, no evidence that harvest or use of these harms environment and they are great tools for making dead soil fallow and useful for growing food crops.
Disagree with classifying plant-derived substances as pesticides
Say proposal is ridiculous, think this is a change
Humic acids aren't CPPAs, and without testing methodology, don't see how EPA can issue such guidance. Want humic acid and SE off of Table 4.
More research needed before putting PBS in same category as pesticides, think this is a regulatory move, say it will affect small farmers

HSE	Ex. 5 Deliberative Process (DP)	
H		
HSE		revise
HSE		
HFK		
HSE		revise
HSE		
HK		
HKSi		
HSE		Revise

0139	K. Reardon, Responsible Industry for a Sound Environment	Industry/Trade Group/Grower/Farmer
0140	S. McCarty, Helena Agri-Enterprises, LLC	Industry/Trade Group/Grower/Farmer
0141	J. Buck, Bio-Gro Inc	Industry/Trade Group/Grower/Farmer
0142	Anonymous	Private Citizen
0143	Anonymous	Private Citizen
0144	R. Tribble (listed as Anonymous - says "allow us to continue using kelp and humics without additional fees so I'm putting as industry/trade etc)	Industry/Trade Group/Grower/Farmer

Similar to some others. Talk about various uses of PBS in ag and non-ag applications, don't want PBS treated as pesticides. 1. claims-based reg approach: think this isn't reflected here, want table 4 removed. Say something is only a pesticide if such a claim is made, and table 4 strays from that. Say dual use concept (pesticide + non-pesticide) should be included in guidance. Table 4 doesn't provide clarity to manufacturers seeking to maintain compliance, it just re-states public info. mention EU treatment of biostims more like fertilizers. Want clarification that other tables aren't comprehensive, suggest clarity on some examples ie enhances/promotes phrasing is overly broad, want them removed from table 3 (bullets 1, 2, 14, 15). Want coordination with other agencies and to wait for definition until after USDA and other stakeholders weigh in. Potential negative effects of proposed guidance: impacts on innovation and companies in biostim market. Think it's shift in regulatory framework. Want table 4 out since they think it requires addl registrations.

Want clarity on exactly what claims require EPA registration. Say clearer definition of PBS would take away the guesswork when categorizing document as PBS or PGR. Think industry and EPA should work together to do that.

Letter appears to have been drafted by Humic Products Trade Assoc. Want definition of PBS as presented in 2018 Farm Bill to be clarified, and EPA wants to align with the definition in the USDA report to Congress, says EPA should wait before finalizing. Mentions history of why some would want to get FIFRA registration to satisfy complicated state registrations. They have specific expertise in HF, listed in Table 4. They agree that soil amendment exemptions for soil-applied HFs should be maintained, but disagree with the proposed language in draft that restricts foliar-applied HF. Say compositional differences should be considered, bring up use of CPPA category, discrepancies in what may actually be registered vs other products. Say guidance doesn't consider the exemptions at 152.15a-c, regarding other commercially valuable uses. Say Humic substances are used for non-pesticidal uses with significant commercial value. They say there will be added burden as a result of guidance even though EPA says otherwise.

"More research is needed"

Request definition of PBS, want guidelines in place to regulate PBS to confirm that the claims actually provide the stated benefits, and having clearer understanding of the intended/potential benefits may provide clarity, and say that while this may increase cost of entry for some, it will provide transparency to growing industry of products for all users

Kelp and humics shouldn't be considered pesticides, protection against pests is indirect not direct, fees will be detrimental to farmers everywhere

	Ex. 5 Deliberative Process (DP)	
		remove
HF		remove
HK		

0145	Anonymous	Private Citizen
0146	Anonymous	Private Citizen
0147	Anonymous	Private Citizen
0148	Anonymous	Private Citizen
0149	T. Lown, Earthgreen Products Inc	Industry/Trade Group/Grower/Farmer
0150	Anonymous	Private Citizen
0151	J. Mirenda, Organic Trade Association	Industry/Trade Group/Grower/Farmer
0152	W. Harrell, Harrell's	Industry/Trade Group/Grower/Farmer
0153	J. MacKay, Cool Planet Energy Systems	Industry/Trade Group/Grower/Farmer

Think guidance is step toward differentiating what is pesticidal/growth regulator, they want allowances for naturally-derived substances that have some ingredients from table 4, mention multiple mechanisms some of which target abiotic stress resistance/relief. Suggest biostimulant class within the minimum risk pesticide listing.

Say this is dangerous, hinders organic farmers.

Including HK is absurd, they're beneficial, aren't pesticides

Say this change in classification without further research would be costly and careless, say these are natural fertilizers and soil conditioners, not pesticides, changes would hurt small family farmers.

Feel classifying biostimulants as pesticides will have broad and harmful effects, inhibit innovation, impede trend toward sustainable agriculture

HSE don't belong as pesticides or in table 4, need more research

Have questions about purpose and intent of Table 4, whether it means all products containing those ingredients are automatically subject to FIFRA regulation regardless of claims/intended use, if that's the case they have concerns about alignment with EPA policies, USDA organic regs, and impact on organic ag sector. They support further coord with USDA to provide clarity on PBS. Table 4-specific comments: it doesn't mention claims at all and doesn't say whether other products need to be registered - unclear impacts. Want clarity around the purpose of Table 4, how it relates to earlier tables (ie is table 4 intended to list ingredients that MAY be subject to FIFRA IF they also have label claims matching table 3?) They've provided labels of things that contain ingredients from Table 4 but no claims similar to Table 3. Quote parts of CFR re: "intended to..." part of PR definition, claims/states/implies use for pesticidal purpose parts. Propose removing Table 4, but also say if instead it stays in, its purpose must be clarified and EPA must encuse that Table 4 is an exhaustive, inclusive list of all affected substances. Propose new name to add "...and associated product label claims..." in it. Also want PBS definition to be aligned with USDA report to congress.

Very similar to some other letters (0080, 0060) - split into 5 categories, ongoing reg uncertainties, impacts on innovation, economic implications, market access for PBS, accessibility for end users. No new info that doesn't appear in the others.

Supplier of biochar, member of Biostim Coalition and Crop Life America, support comments from both. Consider PBS distinct from PGR, say the intentions/claims are to support optimal nutritional processes that enable plant to realize its innate genetic growth potential. Want clearer def of PGR. Say global regulation of PBS is moving towards claims-based approach, treatment as fertilizer. Think lines 267-268 defining nutritional chems thinks many PBS would fall into that category, want EPA to define all statutory exclusions, includ possible definition for nutr chem. Also want EPA to revisit current prohibition on using vitamin hormone products on food sites. Say it's premature for EPA to define PBS.

0154	R. Taylor, Humic Products Trade Assoc	Industry/Trade Group/Grower/Farmer
0155	J. Restum, Scotts Miracle- Gro Co	Industry/Trade Group/Grower/Farmer
0156	P. Mullins, Brandon Products	Industry/Trade Group/Grower/Farmer

Want EPA to wait and work with USDA on definition for PBS. Say Table 4 doesn't appear to be claims-based - want it removed. Disagree with proposed language to restrict foliar-applied HF, bring up composition/identity of CPPA in table. Talk about their endorsed test methodology. Lots of overlap with other comments. Say humic substances have significant commercial value for non-pesticidal uses (soil improvement uses), want nutritional chemicals to be defined.

Supportive of clarification, but want substantial revisions. Say EPA's proposed definition of PBS is inconsistent with others, there's contradiction with respect to plant regulator claims vs plant nutrients, soil amendments and inoculants. Want EPA to postpone rulemaking to define PBS until a federal definition is finalized as envisioned by Congress, differentiate the effect of PRs from natural stimulation and growth enhancement resulting from optimal nutrition, and eliminate list-based guidance by deleting table 4. Go into more detail on each of these. Call out that EPA limits PBS to naturally-occurring and missed synthetic analogs, implying that they're subject to registration as regulators. Also mention impacts on mixing with inorganic/synthetic fertilizers. Want changes in earlier tables, basically saying there's a lack of clarity around some of the growth claims and what does/doesn't require registration. Say the tables are helpful in understanding EPA's intent but don't align with regulations. Say Table 3 should be narrowed to only list claims that are strictly consistent with regulator def in FIFRA 2(v). Want title of Table 1a to be changed to specify nutrition-based claims (necessary for normal plant growth). Say table 4 creates list-based approach, doesn't recognize MOA or intent, erroneously includes plant food ingredients, and shouldn't differentiate between foliar and soil applications. Says proposed guidance doesn't account for concentration needed for something to be biologically active. Mention especially for H that it's unclear of physiological MOA when applied as foliar fertilizer, so classifying them as pesticides that way is unsupported by the literature.

Concerned mostly about seaweed/SE, say it's unclear if including SE on Table 4 means it must be registered under FIFRA, as there are numerous examples of it being sold for nutritional/biostim effects. Say it needs to be made clear that materials registered under FIFRA are not prevented from being marketed as biostims outside of the scope of FIFRA. Mention inhibition of innovation, economic impacts on sm/med biz, deprive growers, say much of the data for SE under FIFRA was pre-2000, based on outdated methodology, applied at such low level that the hormones can't have the PGR effects. Say 152.15 2 b would be good safeguard to make sure pesticides don't get to market incorrectly. Include appendices countering some of the basis of assessment on SE composition, effects of nutrients acting in PGR-like manner.

HF

remove

Ex. 5 Deliberative Process (DP)

HFKSESi

remove

SE

0157	B. Glenn, Natl Assn of State Depts of Ag	State Association of Regulatory Officials
0158	G. Beattie, Phytopathological Society Public Policy Board	Industry/Trade Group/Grower/Farmer
0159	C. Wolfe, FBSciences	Industry/Trade Group/Grower/Farmer

Say guidance falls short of the clarity they need, and instead they need a clear, transparent, coherent regulatory framework. Urge EPA to not finalize guidance until USDA Farm Bill process is done, and encourages EPA to work with states to not unnecessarily bring products that are already registered in the states into FIFRA's registration process. They appreciate Tables 1-3 but are concerned that they may be utilized to bring products which have fertilizer/biostim impacts on plants and soil under FIFRA. Also suggest EPA work with states to determine best approach on dual-use products. Want EPA to work with states to not bring thing over unnecessarily, say some of the claims in Table 3 conflict with state laws.

"enhance/promote/stimulate plant growth and development" and

"enhance/promote fruit growth and devel" are examples - say some state laws define fertilizers as substances with nutrients that promote or stimulate plant growth. Also say table 4 is a departure from the intent and could conflict with state law - it includes lots of ingredients already regulated as fertilizers by states.

Nonprofit scientific organization. Definition of PBS: no single definition is currently universally accepted or serves as a legal definition under FIFRA. They say EPA should wait for coordinated definition to be agreed upon as result of Farm Bill. After that, legal definition is needed so a reasonable regulatory framework can be established. They acknowledge that claims are key consideration but other factors including ai, intended uses, etc are also considered in determining if a pesticide - but that said, they think table 4 may trigger unwarranted hurdles by authorities (like at state level), and say a list of MOA that trigger regulation under FIFRA would be more accurate and get away from fear of a substance-based approach. Talk about difficulty differentiating between growth enhancement (non-FIFRA) and growth regulation (FIFRA), especially as some function in tolerance to abiotic AND biotic stresses. Suggest EPA, USDA, and stakeholders work together for appropriate and sensible regulation. Requested editorial change at line 53 - description of PBS which they say is poor representation of some PBS (ie rhizobia provide N which is a fertilizer benefit, but PBS description in DG says PBS do not provide any nutritionally relevant fertilizer benefit (this was slightly edited in updated DG on p 4 in background).

They registered CPPAs (bullet 5 of table 4), and along with it but incorrectly associated is humic acid, fulvic acid, tannins, organic acids from leonardite. They say CPPA is exclusive to FBSciences, they use proprietary manufacturing process, it's not a generic class of substances. They want Table 4 revised so CPPA is separated from other organic acids

HSESi		revise or remove
	Ex. 5 Deliberative Process (DP)	
		remove
		revise

0160	R. Kachadoorian and L. Reed, AAPCO	Industry/Trade Group/Grower/Farmer
0161	D. Beaudreau + K. Jones, US Biostim Coalition and Biol Products Industry Alliance	Industry/Trade Group/Grower/Farmer
0162	C. Kamberg, TriYield	Industry/Trade Group/Grower/Farmer
0163	BASF	Industry/Trade Group/Grower/Farmer
0164	Humic Products Trade Assn et al on behalf of M. Turner, Catalyst Product Group	Industry/Trade Group/Grower/Farmer

Say state pesticide and fertilizer laws determine if product requires registration. Want effective and consistent regulatory action at state and federal levels. Say more exempt categories results in increased burden on states. They're in favor of requiring registration. Want details and references in table 4 expanded, enforceable language added, details on what enforcement would look like, ensure that reference tables can be edited and updated without opening rulemaking process, and provide clarity on what products can be used on food or feed crops, tolerance issues, etc. Say microbial biostimulants have not been adequately addressed. Want a "PRIA Lite" review framework for biostims. They're glad table 4 is present.

Very extensive comments, including line by line suggestions. Serve as basis for 0060, 0080, 0152, 0162, 0061, and others. Included 15 page proposed addition to the guidance addressing nutritional chemicals excluded from the definition of plant regulators. A lot about optimal growing conditions and how PBS aid a plant without going beyond those limits (innate growth potential etc). Mention dual use situation (as a pesticide and not based on claims). Want clarity on definition of plant regulator in guidance, including decision tree idea. They also include historical perspective on how some things were registered, calling inclusion of HFSE especially problematic. Say that assuming a raw material will also be processed to be made into a pesticide is unreasonable. Also include in depth economic analyses.

Similar to 0080, 0060, 0152.

Support the comments of Biological Product Industry Alliance (BPIA) and Biostimulant Coalition (BC) comments. Also have some specific comments: lines 104 and 110 want amended to include concept of commercially efficacious pesticide, as low level pesticidal activity is not commercially relevant and shouldn't be regulated under FIFRA. lines 134-141 - want definition amended to account for microbial secondary metabolites that may function as vitamin hormones but would be excluded from category. Also want table 4 removed, saying it doesn't align with the DG saying it's intended to provide guidance on identifying product label claims that are considered to be PR claims by agency", since the table is substance-based not claims-based.

Similar to 0080, 0060, 0152, 0162, 0061, 0073, 0071, 0059, 0064, 0076, 0054, but some additional documents. Mention stigma of EPA registration in organic community, say having to do EPA registration would ruin their business, they're only naturally doing what soil and plants naturally do. Think all products with HFSE would need to be registered. Say they're just trying to make healthy soil, add organic content. Want alignment with USDA definition of PBS in report to congress, want EPA to wait for that. Say design of table 4 is divergent from claims-based outline of DG. Also mention CPPA/H issue, lack of clarity of materials.

	Ex. 5 Deliberative Process (DP)	
HFSE		remove
HF		remove
		remove
HFSE		remove

0165	J. Skillen, Lawn & Horticultural Products Work Group	Industry/Trade Group/Grower/Farmer
0166	M. Key, Impello Biosciences	Industry/Trade Group/Grower/Farmer
0167		US State

Incorporation of PBS into specialty consumer products is rapidly growing. Say DG has lots of info but little guidance. Want agency to include decision tree, and they drafted one. Mention states' role in regulating fertilizers. Propose a slightly narrower definition of PBS, mention that EPA does not have its own definition of plant hormones - ask if it's "naturally occurring hormones extracted from algae, such as auxins, cytokinins, and gibberellins". Think EPA should consider revising all definitions under what's exempt, ie plant nutrients, inoculants, soil amendments. Point out lack of clarity by including SE on Table 4 as pesticides, but then saying they don't have a defined content of PGRs and might reasonably be vitamin-hormone products. Spell out why a grower would want to use PGRs: to control/delay abscission/development/ripening/senescence, induce/promote/retard/suppress flowering, induce/promote/retard/suppress bud break, or induce/promote/retard/suppress seed germination. They suggest defining PGRs as substance or mixture of substances that, once applied, alter through physiological action the normal development of the target plant(s) to benefit the grower.

Specializes in R&D of plant biostims, focusing on plant growth promoting rhizobacteria (PGPR) and beneficial microbes. Comments call into 5 categories - ongoing reg uncertainty, impacts on innovation, economic implications, market access for PBS, accessibility for end users - lots of overlap with -0060. They also call out the proposed differentiation of methods of delivery, which introduces confusion and inconsistencies - say it's inaccurate to assume a single ingredient can be pesticidal and non-pesticidal depending on method of delivery, mention claims-based review. Say PBS is helping to revive the ag industry overall.

DPR wants EPA to develop a PBS definition, which will help in making determinations whether products require registration and provide distinction between what is regulated and what is excluded. DPR suggests descriptors in Table 3 to include "vigorous growth", "encourages growth", "earlier maturation", and some others. To table 4, they suggest addition of variations of term SE like concentrated seaweed, derived from kelp, algae of the sea, etc. Wants to know if list will be updated as new AIs are registered. Bring up cytokinins and gibberellins - say that on p10 it says that Table 4 lists things that have MOA and associated label claims that trigger registration, ut label review manual says cytokinins and gibberellins trigger registration without claim since they have no use other than as PGR. Is EPA changing this? Request clarity on some specific claims and whether they'd be PGR claims or not: "is a plant and soil vitality booster featuring a natural blend of cold processed seaweed that encourages thriving growth of roots, stems, and foliage", "these fungi build a natural microbial system in and on plant roots which greatly enhance plant growth and vigor", "is a carefully selected blend of natural and organic fertilizers formulated to encourage multiple blooms and seed formation"

	Ex. 5 Deliberative Process (DP)	
		remove

File Number	Submitter	Submitter Category
0007	Anonymous	Private Citizen
0040	L. Mayhew	Private Citizen
0145	Anonymous	Private Citizen
0131	Anonymous	Private Citizen
0026	Anonmyous (commercial plant grower)	Industry/Trade Group/Grower/Farmer
0087	Anonymous	Private Citizen

Comment summary	Humic or Fulvic Acid/Kelp/Seaweed Extract/Silica (H, F, K, SE, Si or combo) should be removed/not considered pesticide or are at the least nuanced
Praise the guidance but write about abiotic stressors impacting fruit yield/size, and say reducing abiotic stress is exempt but fruit yield/size isn't, so this should be exempt since it is due to abiotic stress reduction.	
various substances are being called pesticides that shouldn't, and they think this guidance is a change in the framework.	HFSE
Think guidance is step toward differentiating what is pesticidal/growth regulator, they want allowances for naturally-derived substances that have some ingredients from table 4, mention multiple mechanisms some of which target abiotic stress resistance/relief. Suggest biostimulant class within the minimum risk pesticide listing.	HFK
Minimum risk pesticide listing mentioned, mention high level of safety and efficiency	HFK
Commercial plant grower, thinks like of these biostimulants that aren't labeled or registered as pesticides or fertilizers, don't know what's in them, but think what makes them beneficial would be identical to other items registered as pesticide or fertilizer. Thinks EPA should require the registrant to show how product works and what AI is, then determine if AI is a pesticide or a fertilizer.	
Do more research before banning such amazing products	

Point(s) in RTC that responds (or none or N/A) - some may be addressed in additional points in a tangential manner	Table 4 - Revise or Remove? (is this what commenter wants, not is this EPA's recommendation)
Ex. 5 Deliberative Process (DP)	

0043	Anonymous (rancher)	Industry/Trade Group/Grower/Farmer
0097	Anonymous	Private Citizen
0129	R. Hudak, Ag BioTech, Inc.	Industry/Trade Group/Grower/Farmer
0107	Anonymous	Private Citizen
0008	Anonymous (but they make comments that sound like they're industry-related, ie "our internal report", "industry questions why EPA...")	Industry/Trade Group/Grower/Farmer

Think this is a rule, thinks it is a way for big corporations to bankrupt organic fertilizer movement	
Proposal is bad, classifying natural organic products as pesticides harms organic farmers/retailers, this is propaganda from big ag	
Wrong to classify PBS with other regulators and pesticides, especially as USDA NOP approves these for organic input. Mention methods through which the biostims work, say including them with pesticides is confusing, will have severe impacts on end users' choices, small business impacts, so PBS shouldn't be included in these "proposed regulations", should either be exempt from registration or in separate category without stringent oversight	
Says this is all about money, EPA wants to regulate things that give life as pesticides, refer to this as new regulation	K
Say guidance does a good job explaining what compounds should and shouldn't get regulated as pesticides, except for HF, tannins, organic acids from leonardite, since they're part of a normal plant living environment. They shouldn't be in table 4. Say approx 50% of carbon in soil is sequestered in stable forms of humic substances, say regulating these substances would have no impact on human exposure to them, discuss some methodology for measuring fulvic acid components. They mention the current rule at 7 CFR 205.203(d)(2) states that humic and fulvic acids must come from a mined mineral, but they believe that isn't being followed in all cases. Industry questions why EPA is listing humic and fulvic acids in same grouping at CPPA, say there are data showing they behave differently and humic substances shouldn't be regulated as pesticides. Say table 4 should be revised so it doesn't encompass a majority of earth's humus and instead list specific known active compounds without HF, tanins, organic acids from leonardite.	HF

Ex. 5 Deliberative Process (DP)	
	revise

0056	H. Damm, Damm Corporation	Industry/Trade Group/Grower/Farmer
0051	Anonymous	Private Citizen
0075	K. Davis, WA State Dept of Ag	US State

<p>Sell liquid fertilizers to organic market, and several of the blends include HFSE. They're opposed to including those as pesticides - say using these substances as generic raw materials shouldn't trigger oversight. Want guidance to focus on product claims, not meterly presence of these ingredients. Very similar to earlier comment (0079)... say as long as no pesticidal claims, shouldn't need to be registered. Want table 4 either revised or removed. Also want clear definition of PBS. Specific questions: does amount of plant regulator make a difference? At what volume, weight, or concen is a PR effective? How will EPA coordinate with States, NOP, or AAPFCO requirements? When will EPA or appropriate agency define PBS?</p>	<p>HFSE</p>
<p>Say confusion arises because of inclusion of SE in table 4, as there are many types of SE with diff chemical compositions and no universally accepted MOA. Mention the varying concentrations of things like auxins, cytokinins, gibberellins, and the fact that SE also comtain carbohydrates, trace elements, AAs, vitamins, nutrients, etc, all of which vary based on source/timing of harvest, and there's no clear understanding of what component plays what role on plant health. Therefore it isn't appropriate for EPA to consider all SE subject to FIFRA on MOA basis. Mention that DG says PBS are relatively new, but SE have been used for centuries. Mention that many effects of SE could be considered non-pesticidal. Say SE have been considered plant nutrients for years. Mention what other commenters have said, including that it's not clear if the benefits of using SE are from the presence of phytohormones that appear to be triggering PGR consideration. Want SE out of table 4. Also say SE should be added to minimum risk pesticides.</p>	<p>SE</p>
<p>Say guidance will be useful to State staff regulating pesticides and fertilizers. Say table 4 is one of the most valuable parts as it makes clear that certain ingredients are pesticides and should be regulated as such. Some line by line comments, including that the guidance doesn't cover all types of PBS like some Bacillus strains - want adding "or biopesticides" after "plant regulators". Want us to wait to develop PBS definition, point out that PBS aren't new and reference 1993 registered product calls a biostimulant. Say not all PBS are natural so that should be removed from EPA's description - they provide some suggested edits/additions. Want it clearly stated that biostimulant is, not by itself, a pesticide claim - want additional clarity. Want MOA considered in addition to label claims, say many PBS products include claims for secondary effect that aren't pesticidal, but MOA of product is as pesticide (example: hormone to increase root growth by MOA, but label claim is increased nutrient uptake). Table 1a - "soil" in several bullets should be removed from 1a and moved to 1c. Request clarification around what "behaviors" are included as physiological actions. Promotion of plant growth can be a nutrient/fertilizer claim. Table 4 question - do the ingredients need to be associated with pesticide claims on label/labeling to be considered pesticide? Lots of table 4 comments regarding clarification (but say it needs to stay).</p>	<p>HFSESi</p>

Ex. 5 Deliberative Process (DP)	
	revise or remove
	revise

0078	G. Orr, Verdesian Life Sciences LLC	Industry/Trade Group/Grower/Farmer
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Concerned that EPA definition of PGR is overreaching and will encompass many/all products fitting PBS definition. Say states are already basing decisions on the DG. Suggest that tables 1-3 be footnoted to remind user that guidance is nonbinding and to say list of claims is not exhaustive. Have issues with EPA's description of what a PBS is: say definition is about substance not product while FIFRA is a labeling law based around product's purpose (they talk about dual-use scenarios), say it shouldn't be limited to naturally occurring Als, conflates definition of soil amendment and PBS (soil amendment definition says ...intended for purpose of improving soil characteristics favorable for plant growth, so there's overlap), mentions that natural processes stimulated by PBS are physiological in nature, saying it will push all PBS in PGR category (so should try to clarify what that means in document..), fails to explicitly state that increases in crop qual/yield are stated objectives in farm bill PBS definition provided for mandated USDA report to congress. Say inclusion of Table 4 is problematic, want it removed, but also provide some specific edits: corn gluten meal is FIFRA 25(b) pesticide exempted from reg, micronutrient salts of humic substances are recognized nutrient source, including with foliar application, SE can elicit responses akin to auxins, cytokinins, gibberellins but the extracts do not contain signif levels of these hormones, AAs are source of nitrogen, Silicates are plant nutrients... Want PBS definition/description to say soemthing like "a nutritional chemical product consisting of a substance or substances that act to improve a plant's natural nutrition processes independent of the substance's nutrien content, thereby improving nutrient availability, uptake, or use efficiency, tolerance to abiotic stress, and subsequent growth, development, quality, or yield". Also want vitamin and hormone exemption extended to food crop uses.

HSESi

Ex. 5 Deliberative Process (DP)

revise or remove

0081	M. Brooks, Ag-Chem Consulting on behalf of Plant Health Intermed	Industry/Trade Group/Grower/Farmer
0167		US State

<p>Want increased clarity from EPA on types of product label claims that amount to PR claims and development of definition of PBS. Want more comprehensive guidance, especially with respect to what is a pesticide/PR and what is an exempt plant nutrient, vitamin hormone product, or something in between but also exempt. Say since congress intended to exempt many PBS from FIFRA regulation, EPA should develop its own definition of PBS, including to make it clear that many/most naturally-occurring PBS are exempt because they are intended for use as something other than PGR. Line between PGR and fertilizer needs to be clearer, highlight the FIFRA definition of PGR excluding substances to that extend that are intended as plant nutrients etc. Say the 2018 Farm Bill definition of PBS is basically fertilizer definition. Want agency to develop its own independent definition. Say DG fails to provide clear, comprehensive guidance on full scope of PGR claims, Als that subject products to FIFRA reg: can products exempted as vit-horm still make PGR claims? 25(b) products make pesticidal claims bc they're exempt from registration, so vit-horm should be able to make PGR claims. Don't like that table 3 is not comprehensive - want it more explicit. Also, want to know about products that contain Als from Table 4 but do NOT make PR claims. Say DG makes no connection between label claims and Als - want that explicitly clear. Request a 2 year grace period in registrations/label revisions.</p>	
<p>DPR wants EPA to develop a PBS definition, which will help in making determinations whether products require registration and provide distinction between what is regulated and what is excluded. DPR suggests descriptors in Table 3 to include "vigorous growth", "encourages growth", "earlier maturation", and some others. To table 4, they suggest addition of variations of term SE like concentrated seaweed, derived from kelp, algae of the sea, etc. Wants to know if list will be updated as new Als are registered. Bring up cytokinins and gibberellins - say that on p10 it says that Table 4 lists things that have MOA and associated label claims that trigger registration, ut label review manual says cytokinins and gibberellins trigger registration without claim since they have no use other than as PGR. Is EPA changing this? Request clarity on some specific claims and whether they'd be PGR claims or not: "is a plant and soil vitality booster featuring a natural blend of cold processed seaweed that encourages thriving growth of roots, stems, and foliage", "these fungi build a natural microbial system in and on plant roots which greatly enhance plant growth and vigor", "is a carefully selected blend of natural and organic fertilizers formulated to encourage multiple blooms and seed formation"</p>	

Ex. 5 Deliberative Process (DP)	